EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	Hon. Robert B. Kugler Hon. Joel Schneider Civil No. 1:19-md-2875-RBK-JS

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.'S AMENDED OBJECTIONS TO PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO ALL API AND FINISHED-DOSE MANUFACTURING DEFENDANTS

In accordance with Case Management Order No. 10 (Dkt. 141) and Case Management Order No. 12 (Dkt. 185), and in accordance with the parties' agreement on November 5, 2019, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") serves these amended objections to Plaintiffs' First Set of Requests for Production of Documents to All API and Finished-Dose Manufacturing Defendants ("Requests").

GENERAL OBJECTIONS

1. ZHP objects to each request to the extent that such request can be read to be seeking the re-production of documents—such as the ANDA files, DMFs, and FDA communications—already produced pursuant to the Court's order on core discovery (Dkt. 88). ZHP incorporates this general objection into the Specific Objections in sections VI (ANDA and DMF), VIII (Manufacturing), IX (Bioequivalence), X (Testing), XI (Nitrosamines and Contamination), XII (Regulatory Correspondence and Documents), XIII (Complaints and Recalls), XIV (Warranties and Statements), and XVI (Identification of Purchasers), all of which overlap to a certain extent with the ANDA files, DMFs, and FDA communications already produced and already subject to ongoing supplementation obligations under the Court's core discovery order (Dkt. 88).

2. ZHP objects to each Definition and Request to the extent that it calls for the disclosure of information protected by any privilege or protection, including without limitation the attorney-client privilege, the work-product doctrine, community of interest privilege, joint-defense privilege, the insurer-insured privilege, the privilege afforded financial records, the right of privacy of any person or entity, and any other available and valid grounds for withholding information from disclosure. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any applicable privilege or immunity. If ZHP withholds any

documents on the basis of any privilege, ZHP will identify those documents in a privilege log consistent with the court-approved ESI Protocol (Dkt. 127). Any inadvertent production of information protected by the attorney-client privilege, prepared in anticipation of litigation or trial, or otherwise protected or immune from discovery shall not constitute a waiver of any privilege nor of any other basis for objecting to the use of such material or its subject matter.

OBJECTIONS TO PLAINTIFFS' DEFINITIONS

2. ZHP objects to Plaintiffs' Definition of the term "Active Pharmaceutical Ingredient" or "API" as overbroad and unduly burdensome in that it is broader than the definition of Active Pharmaceutical Ingredient provided by the FDA and is not limited to Valsartan. ZHP further objects to this Definition as vague and ambiguous in that it includes "any substance or mixture of substances that become the active ingredient of a drug product." For purposes of these Objections, ZHP will interpret and use "Active Pharmaceutical Ingredient" or "API" to have the definition provided by the FDA: "[A]ny substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance." 21 C.F.R. § 207.1; *see also* 21 C.F.R. § 314.3. Further, ZHP will interpret and use "Active Pharmaceutical Ingredient" or "API" to mean Valsartan API.

3. ZHP objects to the Definition of "API Manufacturer" as overbroad, unduly burdensome, vague, and ambiguous, in that it would encompass numerous unidentified entities that manufacture any active pharmaceutical ingredient. For purposes of these Objections, ZHP will interpret and use "API Manufacturer" to mean any entity that manufactures the Valsartan API at issue in these Actions.

4. ZHP objects to the Definition of "Finished Dose Manufacturer" as overbroad, unduly burdensome, vague, and ambiguous in that it would encompass numerous unidentified entities that manufacture any finished dosage form. ZHP further objects to this Definition as overbroad and unduly burdensome in that it encompasses activities beyond those of manufacturing a finished dosage form. For purposes of these Objections, ZHP will interpret and use "Finished Dose Manufacturer" to mean any entity that manufactures Valsartan in a finished dosage form—e.g., tablet, capsule, or solution.

5. ZHP objects to the Definition of "Communication(s)" as overbroad, unduly burdensome, vague, and ambiguous in that it purports to impose burdens on ZHP beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure.

6. ZHP objects to the Definition of "Documents" as overbroad and unduly burdensome in that it purports to impose burdens on ZHP beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure and seeks to expand the definition of ESI beyond the scope set forth in Case Management Order No. 8, Electronic Discovery Protocol. ZHP further objects to this definition's requirement to search "back-up tapes" and all "electronic communications…maintained…in back-up or legacy data formats" as unduly burdensome at this point in time and not reasonably likely to yield non-duplicative, responsive material or information. If, through discovery of electronic documents maintained in the normal course of business in reasonably accessible, non-legacy formats, it is uncovered that additional, non-duplicative, responsive communications reside on back-up tapes or in other archived formats, ZHP is willing to meet and confer with Plaintiffs on the cost and necessity of retrieving that material or information.

7. ZHP objects to the Definition of "Relevant Time Period" as overbroad, unduly burdensome, and not proportional in that it would require production of a decades'-worth of documents, many of which are unrelated to the events at issue in this case. This litigation relates to the sale, purchase, and use of Valsartan in the United States. ZHP did not sell Valsartan API into the United States until January 5, 2015, and did not sell finished dosage form Valsartan into the United States until June 9, 2015. ZHP has already produced the ANDA files and DMF relating to the products allegedly at issue. Accordingly, ZHP objects to the extent Plaintiffs seek information related to Valsartan predating January 1, 2015. However, as stated in Defendants' letter brief on macro discovery issues (Dkt. 290 at 20), ZHP acknowledges that narrowly-tailored discovery into the manufacturing process for Valsartan API may extend to November 27, 2011, the date on which ZHP initiated development of the manufacturing process used on all Valsartan API sold into the United States.

8. ZHP objects to the Definition of "Regulatory and Regulatory Authority" as overbroad, unduly burdensome, vague, and ambiguous in that it would encompass any regulatory agency around the world. Because this litigation involves the purchase or use of Valsartan in

United States, for the purposes of these Objections, ZHP will interpret and use "Regulatory and Regulatory Authority" to mean the FDA.

9. ZHP objects to the Definition of "TPP" as overbroad, unduly burdensome, vague, and ambiguous. For purposes of these Objections, ZHP will interpret and use "TPP" to mean health care providers, plans, and providers as those terms are defined in the Third Party Payor Fact Sheet to be used in this litigation.

10. ZHP objects to the Definition of "Valsartan" as overbroad, unduly burdensome, vague, and ambiguous in that it encompasses both Valsartan API and finished dosage forms. For the purposes of these Objections, ZHP will distinguish between "Valsartan API" and "Valsartan" (finished-dose).

11. ZHP objects to the definition of "You," "Your," or "defendant" as overbroad, unduly burdensome, vague, and ambiguous in that it is to be used "interchangeably" for the parties to which the requests are directed. ZHP will search for and provide information within its possession, custody and control.

DEFINITIONS FOR PURPOSES OF ZHP'S OBJECTIONS

1. "Actions" shall refer to those suits centralized for pretrial proceedings in MDL No. 2875 pending in the U.S. District Court for the District of New Jersey, Case No. 1:19-md-2875.

2. "Active Pharmaceutical Ingredient" or "API" will be interpreted consistent with the definition used by the FDA: "[A]ny substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance." 21 C.F.R. § 207.1; *see also* 21 C.F.R. § 314.3.

3. "API Manufacturer" means an entity that manufactures Valsartan API.

4. "Finished Dose Manufacturer" means an entity that manufactures Valsartan in a finished dose form.

5. "Communication(s)" shall be interpreted in a manner consistent with the ESI Protocol (Dkt. 127) entered in this litigation.

6. "Regulatory and Regulatory Authority" refers to the United States FDA.

7. "Valsartan" will be interpreted to mean Valsartan medications in a finished dose form.

8. References to sales into the "United States Market" refers to Valsartan API sold to holders of approved United States ANDAs or Valsartan sold to purchasers located within the United States.

RESERVATION OF RIGHTS

1. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any applicable privilege or immunity. Any inadvertent production of information protected by the attorney-client privilege, prepared in anticipation of litigation or trial, or otherwise protected or immune from discovery shall not constitute a waiver of any privilege nor of any other basis for objecting to the use of such material or its subject matter. ZHP expressly reserves the right to object to the use or introduction of such information.

2. ZHP's responses to the Requests shall not be construed in any way as an admission that any Definition provided by Plaintiffs is either factually or legally binding upon ZHP. ZHP further rejects the suggestions or conclusions implicit in the Requests. Nor shall ZHP's Objections herein be construed as a waiver of any of ZHP's objections to the use of any response for any purpose, in these actions or any other action, including, but not limited to, objections regarding relevance, discoverability, and admissibility of documents.

3. ZHP reserves the right to supplement or amend these Objections.

4. ZHP's serving of these objections is not, and should not be considered in any manner, a waiver of ZHP's rights, privileges, or defenses, jurisdictional or otherwise. ZHP hereby expressly reserves and preserves all rights, privileges, and defenses available under applicable law.

SPECIFIC OBJECTIONS TO REQUESTS FOR PRODUCTION OF DOCUMENTS

I. CORPORATE ORGANIZATION

REQUEST NO 1: ***Produce organizational charts setting forth the corporate organization for each named defendant, from January 2010 to the present as follows:***

- ***a.*** ***General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of valsartan;***
- ***b.*** ***Medical affairs/clinical affairs department, or the equivalent;***
- ***c.*** ***Quality assurance department, or the equivalent;***
- ***d.*** ***Manufacturing department, including any departments involved in the manufacturing process for valsartan;***
- ***e.*** ***Procurement Department;***
- ***f.*** ***Sales department;***

g. Marketing department;
h. Research and development department;
i. Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);
j. Regulatory department;
k. Department responsible for epidemiology and/or statistical analysis;
l. Professional education department;
m. Department(s) responsible for establishing or maintaining relationships involving valsartan, with any other defendant named in this MDL.

RESPONSE TO REQUEST NO. 1: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to those employees responsible for the design, manufacture, testing, distribution, and recall of Valsartan and Valsartan API. Moreover, the parties have engaged in a series of meet-and-confers to allow Plaintiffs to identify those persons most likely to have knowledge regarding the aforementioned subject matters (*See* Dkt. 185, Case Management Order No. 12), and Plaintiffs have proposed a list of 141 custodians for ZHP and its corporate affiliates. ZHP further objects this Request in that, as written, it is not limited to organizational charts maintained by ZHP in the ordinary course of business; to the extent this Request purports to obligate ZHP to create documentary records that do not exist, it imposes burdens on ZHP beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure. ZHP further objects to this Request on the grounds that the phrases "establishing or maintaining relationships involving valsartan," "professional education department," "statistical analysis," and "procurement department" are vague and ambiguous and could refer to individuals or departments engaged in a wide variety of activity.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it has already produced organizational charts as currently maintained in the ordinary course of business for its API Manufacturing, API Quality Research, Regulatory Affairs, API Quality Assurance, Sales, API Quality Control, and API Technical departments. ZHP also reaffirms its commitment to work through informal discovery methods and in good faith with Plaintiffs' counsel to prepare acceptable and appropriate lists of ESI custodians. (*See* Dkt. 258.)

REQUEST NO 2: ***From 2010 to the present, produce documents sufficient to demonstrate:***

a. All corporate officers;
b. All members of the Board of Directors;

c. All persons or entities which own or owned 5% or more of defendant's commonstock; and [sic]

RESPONSE TO REQUEST NO. 2: ZHP objects on the basis that a Request seeking documents "sufficient" for a particular purpose is vague, ambiguous, and subject to numerous interpretations and, therefore, violative of Plaintiffs' obligation to describe with reasonable particularity each item or category of items to be produced. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information regarding individuals and entities who are not responsible for the design, manufacture, testing, distribution, and recall of Valsartan or Valsartan API and who have no bearing in this product-liability litigation, which centers upon Plaintiffs' allegation that an impurity arose during the manufacture of Valsartan API. ZHP further objects to the extent this Request seeks documents predating the Relevant Time Period. ZHP also objects to this Request to the extent it seeks information that is publicly available or available from another source that is more convenient. ZHP incorporates, by reference, the Rule 7.1 corporate disclosure statements filed before the Judicial Panel on Multidistrict Litigation and the District Court for the District of New Jersey.

REQUEST NO 3: ***To the extent you conduct business relating to valsartan with any other defendant in the above-captioned MDL, produce documents sufficient to demonstrate the nature, extent, and length of this business relationship.***

RESPONSE TO REQUEST NO. 3: ZHP objects on the basis that a Request seeking documents "sufficient" for a particular purpose is vague, ambiguous, and subject to numerous interpretations and, therefore, violative of Plaintiffs' obligation to describe with reasonable particularity each item or category of items to be produced. ZHP objects on the same basis with regard to the phrases "conduct business" and "business relationship," which are undefined and ambiguous as phrased, and could refer to a wide variety of activity from relationships with corporate affiliates to individual sales contracts. ZHP further objects to this Request as duplicative of Requests No. 93 to 111, which seek information related to Valsartan API and Valsartan sales. Furthermore, Plaintiffs have already received an organizational chart from one of ZHP's subsidiaries demonstrating the corporate relationship between ZHP and its Valsartan-related corporate affiliates that are Defendants in these Actions. *See* PRINSTON00079005. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or

defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period or related to sales outside of the United States Market.

By way of further answer, ZHP states as follows:

As Plaintiffs are aware, over 40 entities (and counting) have been named as defendants in this MDL, collectively representing every link in the chain of distribution of Valsartan. Suffice it to say, the relationship between these entities is contractual in nature. Taken literally, this Request would require the production of each and every contract or written agreement entered into between the dozens of defendants named in this MDL—an obvious absurdity. Other than the fact that some Defendants purchased or sold Valsartan API or Valsartan from or to other Defendants, the terms of individual contracts between Defendants in this action are not relevant to any of Plaintiffs' claims.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to agreements for the sale of Valsartan API or Valsartan to any other Defendant in these Actions during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

II. RELEVANT CUSTODIANS

REQUEST NO 4: ***Produce documents sufficient to identify the corporate employees or third parties responsible for or involved in the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof.***

RESPONSE TO REQUEST NO. 4: ZHP objects to this Request as vague, ambiguous, and lacking in particularity, in that it seeks "documents sufficient to identify" corporate employees and third parties and therefore does not identify specific documents with reasonable particularity. ZHP further objects to this Request on the grounds that it is not proportional to the needs of the Actions, as the Court has already set forth a process for the parties to identify relevant custodians for the API and finished dose manufacturer Defendants in Case Management Order No. 12 (Dkt. 185) and has required ZHP to meet in person with Plaintiffs to answer questions related to

corporate structure and custodians (Dkt. 274), and Plaintiffs have proposed a list of 141 custodians for ZHP and its corporate affiliates. ZHP further objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information regarding distribution, packaging, sale, marketing, and communications, which are not job functions that have any bearing on the alleged NDMA or NDEA impurities. ZHP further objections to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks information about employees who communicate with foreign regulatory agencies. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that the topics of testing, purity and contamination, quality assurance, risk assessment, medical and clinical assessments, safety, communications with regulatory agencies, and evaluation are not limited to those functions with respect to the alleged NDMA or NDEA impurities in Valsartan API or to the potential risk of cancer from Valsartan API containing NDMA or NDEA. Even if limited to documents related to Valsartan or the Valsartan recall, the Request is overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks documents to identify *all* employees or third parties "involved in" the various activities for an unlimited period of time, and therefore would require an unreasonable and burdensome search of a large volume of documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. Moreover, ZHP has produced thousands of pages of core discovery documents from which Plaintiffs can identify most, if not all, of the individuals primarily responsible for the various activities listed in the Request, and Plaintiffs have already proposed a list of custodians based on those documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it has already produced organizational charts as currently maintained in the ordinary course of business for its API Manufacturing, API Quality Research, Regulatory Affairs, API Quality Assurance, Sales, API Quality Control, and API Technical departments. ZHP also reaffirms its commitment to work through informal discovery methods and in good faith with Plaintiffs' counsel to prepare acceptable and appropriate lists of ESI custodians. (*See* Dkt. 258.).

III. POLICIES AND PROCEDURES

REQUEST NO 5: ***Produce all documents setting forth all draft and final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.***

RESPONSE TO REQUEST NO. 5: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions insofar as it demands production of "all documents setting forth" a wide range of policies and procedures, including "all draft and final versions." Taken literally, this Request would require ZHP to search for and produce every copy of every policy, procedure, standard operating procedure, or protocol—of which ZHP maintains several thousand—ever created during an unlimited period of time "for or relevant to" 16 broad and undefined categories, which would include emails from ZHP's many employees who receive updated policies. ZHP further objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests information related to distribution, packaging, sale, marketing, and communications, which are not functions that have any bearing on the alleged NDMA or NDEA impurities. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks information about policies for communications with foreign regulatory agencies. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that the topics of testing, purity and contamination, quality assurance, risk assessment, medical and clinical assessments, safety, communications with regulatory agencies, and evaluation are not limited to those functions with respect to the alleged NDMA or NDEA impurities in Valsartan API or to the potential risk of cancer from Valsartan API containing NDMA or NDEA. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. ZHP further objects to this Request in that it seeks "indexes or lists of the requested documents" without limiting that request to documents kept in the ordinary course of business, which purports to impose burdens on ZHP beyond those authorized by Fed. R. Civ. P. 34. ZHP further objects to this Request on the grounds that the terms "policies,"

"procedures," "protocols," and "evaluation," "risk assessment," and "safety," are vague, ambiguous, and lacking in particularity.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery issues, ZHP will endeavor to produce final versions of formal policies and standard operating procedures in its possession that apply or would have applied to Valsartan or Valsartan API sold into the United States Market governing manufacture, distribution, sale, testing for impurities, or recall, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

IV. AGREEMENTS

REQUEST NO 6: ***Produce all formal and informal agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, (16) communications with private individuals or entities, and (17) procurement, with regard to valsartan and/or its ingredients.***

RESPONSE TO REQUEST NO. 6: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it demands the production of "all" documents fitting within seventeen (17) broad categories. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests information related to distribution, packaging, sale, marketing, and communications, which are not functions that have any bearing on the alleged NDMA or NDEA impurities. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks information about policies for communications with foreign regulatory agencies. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that the topics of testing, purity and contamination, quality assurance, risk assessment, medical and clinical assessments, safety, communications with regulatory agencies, evaluation, and procurement are not limited to those functions with respect to the alleged NDMA or NDEA impurities in Valsartan API or to the potential risk of cancer from Valsartan API containing NDMA or NDEA. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because it seeks documents predating the Relevant Time Period. ZHP further objects

to this Request on the grounds that the term "informal agreements" is vague, ambiguous, overbroad and unduly burdensome, and lacking in particularity, as it is subject to different interpretations and could refer to a wide range of activity.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged agreements, contracts, or licenses in its possession, if any, related to the manufacture, testing, distribution, sale, or recall of Valsartan API and Valsartan manufactured during the Relevant Time Period for sale into the United States Market, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 7: ***Produce all documentation, including agreements, draft agreements, memoranda, and physician expense reports, relating, referring to or embodying any attempt by defendant to retain, engage or otherwise provide financial support or item of value to any person with regard to proposed or actual scientific or medical study of valsartan, from January 1, 2010 to the present.***

RESPONSE TO REQUEST NO. 7: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to scientific or medical study of the risk of NDMA or NDEA formation in Valsartan API or the risk of cancer from NDMA or NDEA. ZHP further objects to this Request on the grounds that the term "financial support or item of value" is vague, ambiguous, overbroad and unduly burdensome, and lacking in particularity. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because it seeks documents predating the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to (1) the scientific study of the risk of NDMA or NDEA formation in Valsartan API, and (2) medical study of the risk of cancer from NDMA or NDEA, including final agreements for the retention of any third parties to perform those studies, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms

and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 8: ***Produce all documents relating, referring to or embodying any discussions, negotiations or contracts to engage any third party to represent your interests before the FDA or any regulatory authority, or any Committee or subcommittee thereof, in regard to valsartan, including, but not limited to, retainer agreements or consultant agreements.***

RESPONSE TO REQUEST NO. 8: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome in that it seeks documents related to negotiations to retain third parties which are not relevant to any issue in these Actions. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to discussions with domestic regulatory agencies related to the alleged NDMA or NDEA impurities in Valsartan.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to agreements with third parties to represent ZHP before the FDA related to the alleged NDMA and NDEA impurities in Valsartan and Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 9: ***Produce all documents relating, referring to or embodying the retention of persons in any medical or scientific discipline to study, assess or analyze the safety of valsartan by or on behalf of any defendant, whether retained directly by any defendant or otherwise.***

RESPONSE TO REQUEST NO. 9: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to studies of the risk of cancer from the alleged NDMA or NDEA impurities in Valsartan API. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that it seeks "all" documents related to contracts with third parties, some of which documents may be in

the exclusive possession of such third parties. ZHP further objects to this Request to the extent that it calls for the disclosure of experts retained in connection with pending litigation. ZHP states that it will abide by the expert-disclosure and discovery deadlines established by the Court.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to product non-privileged documents in its possession, if any, related to the retention of third parties to study the potential risk of cancer from the alleged NDMA and NDEA impurities in Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

V. INTRA-DEFENDANT COMMUNICATIONS

REQUEST NO 10: ***All communications between any of the defendants related to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan and/or the ingredients thereof.***

RESPONSE TO REQUEST NO. 10: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests information related to distribution, packaging, sale, and marketing, which are not topics that have any bearing on the alleged NDMA or NDEA impurities. ZHP further objects to this Request as vague and ambiguous in that it requests all "communications…related to…communications." ZHP further objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and irrelevant in that it is not limited to communications with domestic regulatory agencies. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that the topics of testing, purity and contamination, quality assurance, risk assessment, medical and clinical assessments, safety, communications with regulatory agencies, and evaluation are not limited to those functions with respect to the alleged NDMA or NDEA impurities in Valsartan API or to the potential risk of cancer from Valsartan API containing NDMA or NDEA. ZHP further

objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and irrelevant to the extent it is not limited to the Relevant Time Period or to ingredients used in the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged communications in its possession, if any, with other Defendants related to the testing of Valsartan or Valsartan API, the recall of Valsartan or Valsartan API, or the presence of NDMA or NDEA in Valsartan or Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

VI. ANDA AND DMF

REQUEST NO 11: ***To the extent any ANDA file for any valsartan was not produced in whole or in part during core discovery, produce the entire file, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.***

RESPONSE TO REQUEST NO. 11: ZHP objects to the extent this request seeks documents and information related to ANDA files "whether or not ultimately approved" as such documents are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because they are unrelated to products allegedly purchased or used by Plaintiffs. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, as Prinston Pharmaceutical Inc. is the U.S. ANDA holder for Valsartan.

Without waiving the foregoing objections, ZHP states that Prinston Pharmaceutical Inc. has already produced as part of core discovery the two ANDA files for Valsartan marketed in United States.

REQUEST NO 12: ***Produce all correspondence with the FDA concerning any ANDA for valsartan, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.***

RESPONSE TO REQUEST NO. 12: ZHP objects to the extent this request seeks documents and information related to ANDA files "whether or not ultimately approved" as such

documents are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because they are unrelated to the products allegedly purchased or used by Plaintiffs. ZHP further objects to this request as overbroad, unduly burdensome, and not relevant to any claims or defenses in that it seeks production of "all" communication with the FDA irrespective of whether those communications relate to the alleged NDMA or NDEA impurities at issue in these Actions. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, as Prinston Pharmaceutical Inc. is the U.S. ANDA holder for Valsartan.

Without waiving the foregoing objections, ZHP states that Prinston Pharmaceutical Inc. has already produced as part of core discovery the two ANDA files for Valsartan marketed in United States.

REQUEST NO 13: ***Produce all documents containing the list of ingredients in valsartan, which were provided to any regulatory authority, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.***

RESPONSE TO REQUEST NO. 13: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to submissions to the FDA and it requests the production of "all" documents submitted to any regulatory agency, which would require an unreasonable search of ZHP's documents. ZHP sells Valsartan and Valsartan API to customers in 70 countries; there is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Request as vague, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as documents containing "the list of ingredients in valsartan" is not limited to raw materials used in Valsartan API, which is the process identified by Plaintiffs as the source of the alleged impurities. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to the Relevant Time Period.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the ANDA and DMF files and related FDA correspondence produced during core discovery.

REQUEST NO 14: ***Produce all documents relating to New Drug Applications filed by you relating to valsartan, beginning from the date you first began development of the process***

for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

RESPONSE TO REQUEST NO. 14: ZHP objects to this Request as irrelevant in that it seeks documents related to New Drug Applications in litigation involving generic drugs.

Notwithstanding the above, ZHP states that it has not filed any New Drug Applications relating to Valsartan.

REQUEST NO 15: ***Produce all complete drug master files for valsartan.***

RESPONSE TO REQUEST NO. 15: ZHP states that its two Drug Master Files for Valsartan API have been produced during core discovery. ZHP has not submitted any other Drug Master Files for Valsartan API.

VII. LITIGATION AND DOCUMENT PRESERVATION

REQUEST NO 16: ***Produce all document retention or destruction policies in effect from January 1, 2010 to the present.***

RESPONSE TO REQUEST NO. 16: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and seeks documents outside the scope of the Relevant Time Period. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because, in the absence of evidence of spoliation, retention and destruction policies have no bearing on the issues alleged in these Actions. On meet and confers, Plaintiffs implied that this Request is intended to seek production of litigation holds. ZHP therefore objects to this Request as calling for documents protected by the attorney-client privilege, absent a showing of spoliation.

REQUEST NO 17: ***Produce documents sufficient to show the name, case caption, attorney, and/or status of any lawsuit filed against you relating to valsartan contamination.***

RESPONSE TO REQUEST NO. 17: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to cases alleging the presence of NDMA or NDEA in Valsartan API. ZHP further objects to this Request as vague, ambiguous, and lacking in particularity, in that it purports to seek "documents sufficient to show" various aspects of lawsuits and therefore does not identify specific documents with reasonable particularity. ZHP further objects to this Request in that it seeks documents or information that are outside ZHP's possession, custody or control, to the extent there may be

documents filed against ZHP in which ZHP has not been served with process or otherwise notified of said action. ZHP further objects to this request as overbroad, unduly burdensome, not proportional, and irrelevant in that it is not limited to lawsuits filed within the United States. ZHP also objects to this Request to the extent it seeks information that is publicly available through PACER or available from another source that is more convenient, such as litigation alerts that can be established and maintained through Westlaw or Lexis, and that the documents requested are as equally available and accessible to the Plaintiffs herein as they are to ZHP.

Without waiving the foregoing objections, ZHP states that it is not aware of any lawsuits pending in United States concerning the alleged presence of NDMA or NDEA in ZHP's Valsartan or Valsartan API other than those already part of this MDL, filed by Plaintiffs' counsel involved in this MDL, or identified in filings in this MDL. Therefore, the requested information is as equally accessible to Plaintiffs as it is to ZHP. ZHP will endeavor to inform Plaintiffs of any Valsartan actions not filed in and not removable to this Court.

REQUEST NO 18: ***Produce all documents upon which Defendant relies to support each and every affirmative defense asserted in the Answer or which you may assert.***

RESPONSE TO REQUEST NO. 18: ZHP objects to this Request in that it is premature because discovery is ongoing and, moreover, all pleading deadlines have been stayed. ZHP further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. ZHP further objects to this Request as unreasonable in that it fails to identify a set of documents with reasonable particularity as required by Rule 34. ZHP further objects to this Request in advance of any decision on Rule 12 issues, which may narrow the claims and defenses to be asserted in these Actions.

VIII. MANUFACTURING

REQUEST NO 19: ***Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto.***

RESPONSE TO REQUEST NO. 19: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents and "any modifications thereto" related to all aspects of the Valsartan API manufacturing process, without any limitation, when the Master Complaints allege that the NDMA or NDEA was the result of a specific step in the manufacturing process. *See* Personal Injury Master Complaint ¶ 167;

Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan API). ZHP's manufacturing process for Valsartan API involves 6 discrete steps, with a total of 48 sub-steps. *See* PRINSTON00000606–626. Therefore, responding to this Request as written would cause ZHP to search for, review, and produce voluminous documents that are not relevant to Plaintiffs' claims, in that the Request is not limited to the specific step in the Valsartan API manufacturing process that allegedly resulted in the presence of NDMA or NDEA in ZHP's Valsartan API. ZHP further objects to this Request as vague, ambiguous, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as "all documents with regard to the [API] manufacturing process" does not identify any particular set of documents and is duplicative of many other Requests, including Requests No. 20–21 and 23–29. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 20: ***Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in***

valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto.

RESPONSE TO REQUEST NO. 20: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents and "any modifications thereto" related to all machines, materials, and substances involved in all aspects of the Valsartan API manufacturing process, when the Master Complaints allege that the NDMA or NDEA was the result of a specific step in the manufacturing process. *See* Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan API). ZHP's manufacturing process for Valsartan API involves 6 discrete steps, with a total of 48 sub-steps. *See* PRINSTON00000606–626. Therefore, responding to this Request as written would cause ZHP to search for, review, and produce voluminous documents that are not relevant to Plaintiffs' claims, in that the Request is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. ZHP further objects to this Request as vague, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documents with regard to the machines, materials, and substances" does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 21 and 25. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and

summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 21: ***Produce all documents (including photographs or video) with regard to any testing or inspections of the machines, materials, and substances utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan.***

RESPONSE TO REQUEST NO. 21: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents related to all machines, materials, and substances involved in all aspects of the Valsartan API manufacturing process, when the Master Complaints allege that the NDMA or NDEA was the result of a specific step in the manufacturing process. *See* Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan API). ZHP's manufacturing process for Valsartan API involves 6 discrete steps, with a total of 48 sub-steps. *See* PRINSTON00000606–626. Therefore, responding to this Request as written would cause ZHP to search for, review, and produce voluminous documents that are not relevant to Plaintiffs' claims, in that it is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-

related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 22: ***Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto.***

RESPONSE TO REQUEST NO. 22: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents and "any modifications thereto" related to all aspects of the finished dose manufacturing process for Valsartan, when the Master Complaints do not allege, and the FDA has not found, that the finished dose manufacturing process affects the formation or presence of NDMA or NDEA in Valsartan API. Therefore, this Request seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to the testing of Valsartan API using HPLC or GC methods capable of detecting NDMA or NDEA. ZHP further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, or are outside ZHP's possession, custody or control, in that it requests documents from "any . . . affiliated entities," without identifying any specific entities. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-

related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 23: ***Produce all documents identifying any patented device, machine, or technology utilized in the manufacture or testing of valsartan.***

RESPONSE TO REQUEST NO. 23: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests "all" documents related to "any" patented device used in any step of the manufacturing process or in any test, when (1) the Master Complaints allege that the NDMA or NDEA was the result of a specific step in the manufacturing process, *see* Personal Injury Master Complaint ¶ 167, Economic Loss Master Complaint ¶ 327, Medical Monitoring Master Complaint ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan API); and (2) the request is not limited to the HPLC or GC testing methods that are capable of detecting NDMA or NDEA in Valsartan API. ZHP further objects to this Request as it seeks information that is publicly available to Plaintiffs through searches of public databases. ZHP further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, and lacking in particularity, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that Plaintiffs do not allege, and the FDA has not found, that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768. ZHP further objects to this Request to the extent it calls for the disclosure of communications with counsel containing legal advice or other information protected by the

attorney-client privilege or attorney work-product doctrine generated as part of the patent application process.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 24: ***Produce all documents relating to all patents filed by you or employees and/or agents associated with you to any foreign regulatory body regarding any manufacturing processes associated with the creation or manufacturing of valsartan, including all supporting documentation and/or correspondence associated with the filing of those patents.***

RESPONSE TO REQUEST NO. 24: ZHP incorporates the objections to Request No. 23. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to patents held by ZHP but purports to seek documents and information related to "all" patents "filed by" ZHP's employees and/or agents, and "all" supporting documentation and correspondence related to filing, whether or not the patent was ultimately approved and whether or not the machine, device, or process described in the application was used in the manufacture of Valsartan API or finished dose. ZHP further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, or are outside ZHP's possession, custody or control in that it requests "all documents" related to filings with third parties, and thus some documents may be in the exclusive possession of such third parties.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as

memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 25: ***Produce documents which evidence the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof.***

RESPONSE TO REQUEST NO. 25: ZHP objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, and lacking in particularity, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to the supply and testing of ingredients, materials, or components used in the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. ZHP further objects to this Request as overbroad and as seeking irrelevant information in that it is not limited to "evaluation or testing" relating to the potential detection of the impurities alleged in the Actions, namely, NDMA or NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that this Request seeks information unrelated to the manufacture of Valsartan API, which is the process by which Plaintiffs allege the presence of NDMA or NDEA arose. ZHP further objects to this Request on the grounds that the term "evaluation" is vague, ambiguous, and lacking in particularity in that it does not specify what type of evaluation, other than testing, is the subject of this Request. ZHP further objects to this Request as it seeks documents that are neither

relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 26: ***Produce all certificates of analysis or similar documents concerning valsartan, or documents and communications concerning the same.***

RESPONSE TO REQUEST NO. 26: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" certificates of analysis and is therefore not limited to certificates of analysis for Valsartan API or finished dose potentially sold into the United States Market during the Relevant Time Period. For the same reasons, ZHP further objects to this request, in that it seeks "all . . . documents or communications concerning the same." ZHP further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, and lacking in particularity, as it does not distinguish between Valsartan API and Valsartan finished dose. ZHP further objects on the basis that "similar documents" is vague and ambiguous. To the extent this Request seeks certificates of analysis related to the ingredients used to manufacture Valsartan API, ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to certificates of analysis for the ingredients, materials, or components used in the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. To the extent this Request

seeks certificates of analysis related to the ingredients used to manufacture Valsartan finished dose, ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to certificates of analysis for the Valsartan API used in the Valsartan finished dose.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. Furthermore, ZHP will produce certificates of analysis in its possession for Valsartan API potentially sold into the United States during the Relevant Time Period.

REQUEST NO 27: ***Produce complete documentation setting forth (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture/production for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you had or have with regard to potential risks of the use of any solvent utilized including residual or reused solvents.***

RESPONSE TO REQUEST NO. 27: ZHP objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that: (1) it is not limited to lots and batches of Valsartan, whether API or finished dose, distributed in the United States market, and (2) it seeks information about lots and batches that were not subject to any recall. ZHP further objects to this request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable, and not proportional to the needs of the Actions, in that it requests production of "complete documentation." ZHP further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad

and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. ZHP further agrees to produce non-privileged documents in its possession, if any, related to the risk of NDMA or NDEA formation from the use of any solvent used during the manufacture of Valsartan API, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 28: ***Produce all documents relating to all scientific journal articles submitted to any academic or scientific publication written or drafted in whole, or in part, by your employees or scientists who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including any final version, any drafts, edits, peer***

reviewed feedback, as well as all communications regarding any possible submission, acceptance or rejection of those journal articles.

RESPONSE TO REQUEST NO. 28: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents and information related to all aspects of the manufacturing process, and requests production of "all" documents and "all" scientific journal articles, including "any" drafts, edits, feedback, and communications regarding "possible" submissions. ZHP further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, and lacking in particularity, as it does not distinguish between Valsartan API and Valsartan finished dose. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, as it seeks "all" documents related to articles drafted by and submitted to third parties, some of which documents may be in the exclusive possession of such third parties. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. ZHP further objects to the extent Plaintiffs demand the production of published studies and articles that exist in the public domain.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and

summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. ZHP further agrees to produce non-privileged documents in its possession, if any, related to academic or scientific publications on the risk of NDMA or NDEA formation during the manufacture of Valsartan API, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 29: ***All documents and communications between you and any third party, outside consultant, university, or individual scientist regarding the manufacturing process associated with the creation of valsartan, including but not limited to the tetrazole ring formation process. These documents should include requests to study the manufacturing process used to create valsartan, exchange of data regarding the manufacturing process used to create valsartan, requests to draft academic journal articles regarding the manufacturing process used to create valsartan, and all documents sufficient to show the payments made and/or contracts between you and those third parties.***

RESPONSE TO REQUEST NO. 29: ZHP incorporates its objections in response to Request No. 28.

Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. ZHP further agrees to produce non-

privileged documents in its possession, if any, related to academic or scientific publications on the risk of NDMA or NDEA formation during the manufacture of Valsartan API, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

IX. BIOEQUIVALENCE

REQUEST NO 30: ***All documents regarding the bioequivalence of any valsartan sold or manufactured (in whole or in part) by you to the Reference Listed Drug ("RLD"), including but not limited to, testing, correspondence with the FDA, and certifications of bioequivalence.***

RESPONSE TO REQUEST NO. 30: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States during the Relevant Time Period. ZHP sells Valsartan and Valsartan API to customers in 70 countries; there is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it the alleged presence of NDMA or NDEA in Valsartan has no bearing on bioequivalence. ZHP further objects to this Request in that it seeks documents or information that are not known, or are outside ZHP's possession, custody or control, in that ZHP does not hold any ANDAs for Valsartan. Prinston Pharmaceutical Inc. holds the two ANDAs for Valsartan and contracted with third parties to complete the bioequivalence studies for Valsartan. ZHP further objects to this request as vague, ambiguous, and lacking in particularity, as "document regarding bioequivalence" does not identify any set of documents with particularity.

By way of further answer, ZHP states as follows:

As alleged in the operative Master Complaints, the purported NDMA and NDEA impurity occurred during the API manufacturing process. (*See, e.g.*, Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289.) Issues of bioequivalence relate to finished-dosage forms. Without waiving the foregoing

objections, ZHP states that documents relating to bioequivalence studies, correspondence with FDA concerning bioequivalence, and certifications of bioequivalence are contained within the ANDA files and other materials previously produced during core discovery. Further, during the meet-and-confer process, Plaintiffs could not define exactly what information, beyond what has already been produced during core discovery, would be responsive and relevant, but they suggested that this Request was aimed at information concerning the "efficacy" and "safety" of Valsartan. Even putting aside the fact that efficacy, safety, and bioequivalence are not synonymous and this Request refers only to bioequivalence, ZHP states that a demand for all documents regarding the "safety and efficacy" of Valsartan does not describe with reasonable particularity each item or category of items. Indeed, taken literally, every document in Mylan's possession that mentions valsartan could, in some way, be construed as relating to the safety or efficacy of Valsartan.

REQUEST NO 31: ***All documents and communications regarding the equivalence of any valsartan sold or manufactured (in whole or in part) by you to their RLD, including all marketing materials regarding the equivalence of your products with the RLD.***

RESPONSE TO REQUEST NO. 31: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States during the Relevant Time Period. ZHP sells Valsartan and Valsartan API to customers in 70 countries; there is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it the alleged presence of NDMA or NDEA in Valsartan has no bearing on bioequivalence. ZHP further objects to this Request in that it seeks documents or information that are not known, or are outside ZHP's possession, custody or control, in that ZHP does not hold any ANDAs for Valsartan. Prinston Pharmaceutical Inc. holds the two ANDAs for Valsartan. ZHP further objects to this request as vague, ambiguous, and lacking in particularity, as "document regarding the equivalence of" Valsartan does not identify any set of documents with particularity.

By way of further answer, ZHP incorporates its answer in response to Request No. 30.

REQUEST NO 32: ***All documents and communications regarding the identification by any person or entity of any valsartan manufactured, utilized, or sold by or to you as not being bioequivalent to the RLD.***

RESPONSE TO REQUEST NO. 32: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States during the Relevant Time Period. ZHP sells Valsartan and Valsartan API to customers in 70 countries; there is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it the alleged presence of NDMA or NDEA in Valsartan has no bearing on bioequivalence. ZHP further objects to this Request in that it seeks documents or information that are not known, or are outside ZHP's possession, custody or control, in that ZHP does not hold any ANDAs for Valsartan. Prinston Pharmaceutical Inc. holds the two ANDAs for Valsartan.

By way of further response, ZHP incorporates its answer in response to Request No. 30.

REQUEST NO 33: ***All documents and communications relevant to valsartan entries in the FDA's "Orange Book."***

RESPONSE TO REQUEST NO. 33: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States. ZHP further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it the alleged presence of NDMA or NDEA in Valsartan has no bearing on bioequivalence. ZHP further objects to this Request in that it seeks documents or information that are not known, or are outside ZHP's possession, custody or control, in that ZHP does not hold any ANDAs for Valsartan. Prinston Pharmaceutical Inc. holds the two ANDAs for Valsartan.

By way of further answer, ZHP states as follows:

ZHP incorporates its answer in response to Request No. 30. Further, by way of background, the *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by FDA. The main criterion for the inclusion of any product in the Orange Book is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons. It is therefore unclear what information Plaintiffs seek through this Request.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the FDA's Orange Book, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 34: ***All documents and communications regarding any patent litigation between you and either the Brand Manufacturer of the RLD regarding valsartan, or other generic companies which had filed an ANDA application for a valsartan product including all filings, briefings, exhibits, citizen petitions, and/or correspondence with the FDA or another regulatory agency.***

RESPONSE TO REQUEST NO. 34: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents concerning "any patent litigation" regardless of whether they have any bearing on the issues in the Actions, which would require an unreasonable search of ZHP's documents. The Request is also objectionable on the basis that it is unlimited in time and location. ZHP further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses because materials pertaining to intellectual property issues and market entry of finished-dosage forms have no bearing on whether, as Plaintiffs allege, an impurity may have arisen during the manufacture of Valsartan API. ZHP also objects to this Request to the extent it seeks documents or information that is publicly available or available from another source that is more or equally convenient.

By way of further response, ZHP states as follows:

Federal courts enjoy exclusive jurisdiction over patent litigation, *see* 28 USC § 1338(a), and therefore all non-privileged filings and briefings are publicly available through PACER. Likewise, citizen petitions are publicly available at www.regulations.gov. Demands for production

of publicly available information equally accessible to Plaintiffs are beyond the scope of permissible discovery. Moreover, issues involved in patent litigation, including Hatch-Waxman cases, and documents produced in those litigations, have no bearing upon and are irrelevant to any issues in the Actions and to any of Plaintiffs' claims or the Defendants' defenses.

X. TESTING

REQUEST NO 35: ***Produce all documents setting forth the planning, occurrence, or results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.***

RESPONSE TO REQUEST NO. 35: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests "all" documents related to any "impurities and contamination" and is therefore not limited to the alleged NDMA and NDEA impurities at issue in the Actions. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the HPLC or GC testing methods that are capable of identifying impurities like NDMA or NDEA in valsartan. ZHP further objects to this Request on the grounds that the term "planning" is vague, ambiguous, and lacking in particularity, in that it could refer to a wide range of activity. ZHP further objects to this Request on the grounds that the phrase "had the potential to directly or indirectly identify" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the Actions, in that it purports to seek documents that are not directed to the alleged NDMA and NDEA impurities at issue in these Actions.

By way of further answer, ZHP states as follows:

Impurities like NDMA or NDEA can only be identified through HPLC or GC testing, and methods to detect impurities at the levels associated with ZHP's recalls of Valsartan were not developed until after the initial recalls of Valsartan were announced in July 2018. Any other test is not designed to, intended to, or sufficiently sensitive to identify the alleged NDMA or NDEA impurities at issue and are therefore not relevant to these Actions.

Notwithstanding the above, during a meet and confer dated November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and that Plaintiffs may be able to explicitly narrow this request upon the production of certain documents by ZHP. Accordingly, subject to the objections asserted herein, and to the parties' agreement

reached during that meet and confer, ZHP will endeavor to produce (1) HPLC and GC test results for Valsartan API that could have been sold into the United States Market; (2) the Valsartan-related exhibits referenced in the EIRs produced during core discovery; (3) other discrete documents to be proposed by Plaintiffs consistent with the November 8 discussion; and (4) other documents identified by ZHP that provide summaries of the types of testing that ZHP has conducted on Valsartan API. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular testing they determine is material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

REQUEST NO 36: ***Produce all documentation with regard to the first test that indicated contamination of valsartan that was potentially due to a nitrosamine, whether or not identified at the time.***

RESPONSE TO REQUEST NO. 36: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the alleged NDMA and NDEA impurities at issue in the Actions. ZHP further objects to this Request as vague, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documentation" does not identify any particular set or collection of documents and is duplicative of other Requests, including Request No. 35.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP agrees to produce non-privileged documents in its possession related to the first test that indicated that Valsartan API contained NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 37: ***Produce all documentation with regard to each notification to defendant of contamination of valsartan that was, or potentially was, due to a nitrosamine, including the full documentation of the testing and analysis that led to the identification of the actual or potential contamination. In connection with this request, separately identify the first such notification.***

RESPONSE TO REQUEST NO. 37: ZHP incorporates by reference its Response to Request No. 36. ZHP further objects to this Request as vague, ambiguous, lacking in particularity, overly broad and unduly burdensome in that "notification" is undefined and could refer to a wide range of activity.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP agrees to produce non-privileged documents in its possession related to (1) tests indicating that Valsartan API contained NDMA or NDEA and (2) third parties notifying ZHP of Valsartan API containing NDMA or NDEA, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 38: ***Produce all documents or communications with regard to the actual or attempted detection of impurities or contaminants in valsartan or any component or ingredient thereof, including chromatographs, and intermediate testing.***

RESPONSE TO REQUEST NO. 38: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests "all" documents related to any "impurities and contamination" and is therefore not limited to the alleged NDMA and NDEA impurities at issue in the Actions. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the HPLC or GC testing methods that are capable of identifying impurities like NDMA or NDEA in Valsartan. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it purports to seek testing of ingredients used in the manufacture of finished-dose Valsartan, while the Master Complaints allege that the impurities arise from the Valsartan API manufacturing process. ZHP further objects to this Request as vague, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as "all documents and communications" does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 35 and 36.

By way of further answer, ZHP incorporates its answer in response to Request No. 35.

Notwithstanding the above, during a meet and confer dated November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and that Plaintiffs may be able to explicitly narrow this request upon the production of certain documents by ZHP. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) HPLC and GC test results for Valsartan API that could have been sold into the United States Market; (2) the Valsartan-related exhibits referenced in the EIRs produced during core discovery; (3) other discrete documents to

be proposed by Plaintiffs consistent with the November 8 discussion; and (4) other documents identified by ZHP that provide summaries of the types of testing that ZHP has conducted on Valsartan API. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to particular testing which they determine is material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. Furthermore, ZHP will produce non-privileged documents in its possession related to (1) the research, validation, and implementation of the HPLC and GC testing methods for Valsartan API, and (2) identification of NDMA and NDEA in Valsartan API through HPLC and GC testing, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 39: ***Produce all documents with regard to evaluation by an employee of defendant or a third party, of the health risks of valsartan contamination.***

RESPONSE TO REQUEST NO. 39: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests "all" documents related to any "evaluation" of any "valsartan contamination," and is therefore not limited to the NDMA or NDEA impurities at issue in these Actions. ZHP further objects to this Request in that it seeks documents or information that are not known, or are outside ZHP's possession, custody or control, as it seeks "all" documents related to evaluations by any third parties, some of which may be in the exclusive possession of such third parties. ZHP further objects to this Request as overbroad and unduly burdensome, not relevant, and not proportional to the needs of the Actions in that the term "health risks" is not limited to the health risks associated with Valsartan and Valsartan API as alleged in the Master Complaints (i.e., cancer).

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will produce non-privileged documents in its possession, if any, related to the evaluation of the risk of cancer from Valsartan API containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 40: ***Produce all documents relating, referring to or embodying studies on the safety, ingredients, impurities, and contamination, of valsartan conducted by any third***

parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.

RESPONSE TO REQUEST NO. 40: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to studies relating to the impurities, health risks, or ingredients at issue in these Actions and in that it requests the production of "all" documents. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that it seeks "all" documents related to studies conducted by third parties, some of which may be in the exclusive possession of such third parties. ZHP further objects to the extent the request seeks documents available in the public realm equally available to Plaintiffs. ZHP further objects to this Request on the grounds that the term "safety" is vague, ambiguous, lacking in particularity, and neither relevant to any party's claim or defense nor proportional to the needs of each case because it is not limited to the health risks associated with Valsartan and Valsartan API as alleged in the individual and Master Complaints.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will produce non-privileged documents in its possession, if any, related to studies on (1) the potential for the formation of NDMA or NDEA from the Valsartan API manufacturing process and (2) the risk of cancer from Valsartan API containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 41: ***Produce all documents concerning any receipt, discussion, studies, analysis or review of clinical experience reports for valsartan, including, but not limited to, formally submitted adverse reaction reports, communications (whether written or oral), case reports, published clinical experience reports, or any other such report made known to Defendant concerning valsartan including, but not limited to: 1) the relationship between the use of contaminated valsartan and potential or confirmed injuries; b) investigator reported events identified by patient number and relevant records; and c) any employee or consultant who reviewed and/or adjudicated such events for causation.***

RESPONSE TO REQUEST NO. 41: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents. ZHP further objects to this Request as it seeks documents that are neither relevant

to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks case reports, clinical experience reports, and any other reports that are not related to the impurities, injuries, or products at issue in the Actions. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that it requests "all" documents related to reports of third parties, some of which documents may be in the exclusive possession of such third parties. ZHP further objects to this Request on the grounds that the term "investigator reported events" is vague, ambiguous, and lacking in particularity. ZHP further objects to the extent the request for reports "made known" to Defendants seeks public documents equally available to Plaintiffs. ZHP also objects on the basis that the information sought by Plaintiffs is not relevant to or admissible on any issue relevant to these Actions.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will produce non-privileged documents in its possession, if any, related to adverse event reports identifying cancer as a result of ingesting Valsartan, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 42: ***As to any clinical or animal study regarding valsartan, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, provide all documents concerning said study, including, but not limited to, analysis and conclusions, engagement letters, contracts, agreements with investigators, agreements with study locations, protocols, status reports, raw data, summary of findings, internal memoranda, drafts of reports, final reports, manuscripts, submissions to publishers, submissions to any regulatory authority.***

RESPONSE TO REQUEST NO. 42: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to studies related to the NDMA and NDEA impurities at issue in the Actions and requests the production of "all" documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because, to the extent clinical or animal studies may exist, they bear no relation to NDMA and NDEA impurities. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control in that it seeks "all" documents related to studies by third parties, some of which may be in the exclusive control of such third parties. ZHP further objects to the extent the request seeks public documents equally available to Plaintiffs. Further,

Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding "any regulatory authority" is overbroad, unduly burdensome, and not proportional to the needs of the Actions.

By way of further answer, ZHP states as follows:

ZHP has not conducted "animal" studies with respect to Valsartan and any "clinical" study, as ZHP understands that term, would be contained in the ANDA files, which have already been produced as a part of core discovery.

REQUEST NO 43: ***Produce all documents relating, referring to or embodying any epidemiology studies or analyses known to defendant regarding valsartan, including but not limited to, any provided to or received from any regulatory authority, SAS data sets, combined analysis or pooled analysis whether or not published in medical literature or submitted to any regulatory authority, study hypotheses, test protocols, data compilations, summaries of results, drafts of reports, final reports, published or unpublished articles or studies, presentations and poster sessions, compensation, engagement of investigators, investigators' brochures, and internal memoranda.***

RESPONSE TO REQUEST NO. 43: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to testing conducted at ZHP's direction and requests the production of "all" documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to studies or analyses pertaining to Valsartan API containing NDMA or NDEA impurities. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that it seeks "all" documents related to studies "known to" ZHP, but not necessarily within ZHP's possession. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, the production of documents regarding "any regulatory authority" is overbroad, unduly burdensome, and not proportional to the needs of the Actions. ZHP also objects to the extent Plaintiffs demand production of documents in the public domain or relating to injuries other than those allegedly experienced by Plaintiffs.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will produce non-privileged documents in its possession, if any, related to epidemiology or similar studies on the effect of NDMA or NDEA in Valsartan API on the risk of cancer, which ZHP will identify through a reasonable search for

responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 44: ***Produce documents sufficient to show (a) all testing, prior to any recall, of valsartan you manufactured or sourced, (b) all testing, after any recall, of valsartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities or contamination, complete documentation with regard to the reason(s) why no such testing was performed.***

RESPONSE TO REQUEST NO. 44: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests documents related to "all" testing that occurred or did not occur on Valsartan in any form. This Request therefore seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the HPLC or GC testing methods that are capable of identifying impurities like NDMA or NDEA. ZHP also objects on the basis that the Request does not describe with reasonable particularity the documents sought insofar as Plaintiffs demand production of materials relating to any type of "testing . . . not performed" and the "reason(s) why no such testing was performed."

By way of further answer, ZHP incorporates its answer in response to Request No. 35.

Notwithstanding the above, during a meet and confer dated November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and that Plaintiffs may be able to be explicitly narrow this request upon the production of certain documents by ZHP. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) HPLC and GC test results for Valsartan API that could have been sold into the United States Market; (2) the Valsartan-related exhibits referenced in the EIRs produced during core discovery; (3) other discrete documents to be proposed by Plaintiffs consistent with the November 8 discussion; and (4) other documents identified by ZHP that provide summaries of the types of testing that ZHP has conducted on Valsartan API. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular testing they determine is material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers. Furthermore, ZHP will endeavor to produce non-privileged documents and communications in its possession related to (1) the

research, validation, and implementation of the HPLC and GC testing methods for Valsartan API, and (2) identification of NDMA and NDEA in Valsartan API through HPLC and GC testing, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

XI. NITROSAMINES AND CONTAMINATION

REQUEST NO 45: ***Produce complete documentation identifying each lot, batch, or other production quantity of valsartan, and whether and how or why: (a) each was confirmed to be contaminated and the quantification of the contamination; (b) each was assumed to have been contaminated and the quantification of the contamination; (c) each was confirmed not to be contaminated; (d) each was assumed not to be contaminated, and (e) each was not confirmed or assumed to be contaminated.***

RESPONSE TO REQUEST NO. 45: ZHP further objects as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States Market during the Relevant Time Period and requests the production of "complete" documentation concerning "each" lot or batch of valsartan, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request to the extent that the language "complete documentation identifying" purports to obligate ZHP to create a documentary record that does not exist in the ordinary course of business, which imposes burdens on ZHP beyond those authorized by Rule 34. Finally, ZHP further objects to this Request as vague and ambiguous, lacking in particularity, and unreasonable in that it demands production of documents purporting to identify "whether and how or why" medication was confirmed or "assumed" to be "contaminated," which terms are subject to multiple interpretations and are not limited to the alleged NDMA or NDEA impurities in Valsartan API at issue in these Actions.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to testing performed on Valsartan or Valsartan API manufactured during the Relevant Time Period for sale in the United States Market to detect NDMA or NDEA and the results of that testing, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 46: ***Produce all documents with regard to any nitrosamine compound, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic***

contaminant that has been directly or indirectly tested for and/or identified in valsartan or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant.

RESPONSE TO REQUEST NO. 46: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States Market during the Relevant Time Period and requests the production of "all" documents concerning "any" nitrosamine "or carcinogenic contaminant," when Plaintiffs' allegations in their Complaints are limited to Valsartan API containing NDMA or NDEA. ZHP further objects to this Request as unduly burdensome and unreasonable in that, as written, it includes the production of publicly available information such as numerous FDA press releases and other statements. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the Actions, in that it purports to seek information about unspecified "other" impurities that have been "directly or indirectly tested for."

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 47: ***Produce all documents evidencing any testing or research conducted by you to determine the existence or amount of contamination in any valsartan API or finished drug formulation. . [sic]***

RESPONSE TO REQUEST NO. 47: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to testing for NDMA or NDEA of Valsartan API sold or distributed into the United States Market during the Relevant Time Period. To the extent Plaintiffs request the production of documents relating to unspecified other impurities, it is improper and irrelevant.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to testing or research performed by ZHP to determine the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 48: ***Produce all documents and communications with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.***

RESPONSE TO REQUEST NO. 48: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents in a particular category, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this request as overbroad, unduly burdensome, not proportional, and irrelevant in that it requests documents concerning "any" carcinogenic substance and all "health risks," when Plaintiffs' allegations in their Complaints are limited to the risk of cancer from Valsartan API allegedly containing NDMA or NDEA. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the risk of cancer from the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 49: ***Produce all studies, data, or other scientific or medical information reviewed or considered by any employee with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.***

RESPONSE TO REQUEST NO. 49: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents in a

particular category considered by "any" employee, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks studies and data about topics other than the risk of cancer from the alleged NDMA and NDEA impurities at issue in this case. ZHP further objects to this case as overbroad, unduly burdensome, not proportional, and irrelevant in that it is not limited to the Relevant Time Period.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to studies of the risk of cancer from the presence of NDMA or NDEA in Valsartan or Valsartan API that was sold into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 50: ***Produce all formal or informal reports or complaints by or to any person or entity with regard to valsartan contamination.***

RESPONSE TO REQUEST NO. 50: ZHP objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents within a particular category, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited complaints, adverse event reports and similar communications related to the alleged NDMA and NDEA impurities at issue in these Actions. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to the Relevant Time Period. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that it requests all reports "to any person or entity," and is not limited to reports to ZHP.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to reports it received of the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon

search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 51: ***Produce every document relating, referring to or embodying any opinion by a physician, or a scientist, or a medical or scientific expert, given after the first notification of potential nitrosamine contamination of valsartan, regarding the safety or efficacy of valsartan including, but not limited to internal documents, reports prepared in legal proceedings, opinions expressed in depositions or trial, reports submitted to scientific journals, opinions expressed at medical conferences and opinions provided as testimony, reports or statements to the FDA or any regulatory authority, or any advisory committee thereof.***

RESPONSE TO REQUEST NO. 51: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "every" document in a particular category, and therefore would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to scientific or medical opinions about the potential risk of cancer from Valsartan API containing NDMA or NDEA. ZHP further objects to this Request in that it seeks documents or information that are not known to or are outside ZHP's possession, custody or control, in that (1) it seeks opinions by persons or entities in any litigation anywhere in the world, and is not limited to opinions by persons or entities hired or consulted by ZHP, and (2) it seeks "every" document "relating, referring to, or embodying" opinions by third parties, including documents submitted to third parties, and some of those documents may be in the exclusive possession of such third parties. ZHP further objects to this Request to the extent that it calls for the disclosure of experts retained in connection with pending litigation. ZHP states that it will abide by the expert-disclosure deadlines established by the Court.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the risk of cancer from Valsartan or Valsartan API containing NDMA or NDEA that was sold into the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

XII. REGULATORY CORRESPONDENCE AND DOCUMENTS

REQUEST NO 52: ***Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan.***

RESPONSE TO REQUEST NO. 52: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to communications with the FDA regarding the alleged NDMA and NDEA impurities in Valsartan API. ZHP sells Valsartan and Valsartan API to customers in 70 countries, and this Request for "all" regulatory documentation in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used.

Notwithstanding the above, ZHP states that its communications with the FDA related to the ARB recall and its two DMFs for Valsartan API have been produced during core discovery and will continue to be produced consistent with Dkt. 88.

REQUEST NO 53: ***Produce all regulatory documentation and communications with regard to any aspect of the manufacturing process for valsartan.***

RESPONSE TO REQUEST NO. 53: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to submissions to the FDA related to the specific step in the Valsartan API manufacturing process that allegedly resulted in the presence of NDMA or NDEA. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has communicated with numerous

foreign regulatory agencies. Therefore, this Request for "all" regulatory documentation in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documentation or communications with regard to any aspect of the manufacturing process" does not identify any particular set of documents and is duplicative of many other Requests, including Requests No. 20–21 and 23–29.

Notwithstanding the above, ZHP states that its communications with the FDA related to the ARB recall and its two DMFs for Valsartan API have been produced during core discovery and will continue to be produced pursuant to Dkt. 88. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged submissions to the FDA in its possession, if any, related to the specific step in the Valsartan API manufacturing process involving formation of the tetrazole ring, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 54: ***Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan.***

RESPONSE TO REQUEST NO. 54: ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to proceedings with domestic regulatory agencies related to the alleged NDMA or NDEA impurities in Valsartan API. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has communicated with numerous foreign regulatory agencies. Therefore, this Request related to regulatory agencies in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP also objects to the extent this Request seeks information in the public domain or otherwise equally accessible to Plaintiffs. ZHP further objects to this Request as unreasonable in that it is not limited to transcripts, memoranda, or other documentation that ZHP currently maintains in the ordinary course of business.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to proceedings or meetings with the FDA related to the recall of Valsartan and Valsartan API for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 55: ***Produce all documents with regard to any FDA Advisory Panel meetings regarding valsartan contamination, including but not limited to:***

a. ***All documents relating or referring to any communications between Defendant (or any agent or consultant of Defendant), and the FDA or any Advisory Panel Member;***

b. ***All documents relating to or referring to any financial contributions or other items of value provided by Defendant to Panel Members or their institutions/organizations; and***

c. ***All documents relating, referring to or embodying minutes of meetings, agendas, dossiers, submissions, test summaries, internal memoranda regarding strategies and issues, Questions and Answers, scheduling, or any other documents concerning the Advisory Panel, submissions thereto, or the topic(s) discussed.***

RESPONSE TO REQUEST NO. 55: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to the Relevant Time Period or to meetings related to the alleged NDMA or NDEA impurities in Valsartan API. ZHP also objects on the basis that this Request seeks documents in the public realm, equally accessible to Plaintiffs.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to meetings with the FDA related to the recall of Valsartan and Valsartan API for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 56: ***Produce all Establishment Inspection Reports and related documentation (including photographs or video) concerning your facilities or the facilities of any other defendant relating to valsartan or any equipment or systems used in the manufacture, fabrication, packaging, distribution, or sale of valsartan.***

RESPONSE TO REQUEST NO. 56: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and therefore would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to inspections conducted by the FDA on the facility that manufactures Valsartan API. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to documents that address or discuss Valsartan.

Notwithstanding the above, ZHP states that the Establishment Inspection Reports in its possession for the facility that manufactures Valsartan API have been produced in core discovery. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to FDA inspections of the facility that manufactures Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 57: ***Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, and warning letters) or consent decrees which pertain in any way to valsartan contamination or any facility in which contaminated valsartan was manufactured, marketed, distributed or otherwise stored.***

RESPONSE TO REQUEST NO. 57: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and therefore would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to documents related to inspections of the facility that manufactures Valsartan API. ZHP also objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to inspections conducted by the FDA. ZHP further objects to this Request as it seeks documents that are neither relevant to

any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to inspections that relate to the alleged NDMA and NDEA impurities in Valsartan API.

Notwithstanding the above, ZHP states that documents related to FDA inspections of the facility that manufactures Valsartan API have already been produced in core discovery. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to FDA inspections of the facility that manufactures Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 58: ***Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to valsartan, including documentation showing what caused the CAPA to be opened and/or closed.***

RESPONSE TO REQUEST NO. 58: ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period.

Notwithstanding the above, ZHP states that the CAPAs it has submitted to the FDA related to inspections of its facility that manufactures Valsartan API have been produced during core discovery. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce additional non-privileged documents in its possession, if any, related to CAPAs submitted to the FDA related to Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 59: ***Produce all documentation, and related communications, of any complaints or third party communications to or from any regulatory agency with regard to actual or potential valsartan contamination.***

RESPONSE TO REQUEST NO. 59: ZHP objects on the basis that this Request is vague and ambiguous as phrased. ZHP further objects to this Request as overbroad, unduly burdensome,

and not proportional to the needs of the Actions, in that it is not limited to domestic regulatory agencies and it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to the Relevant Time Period or to the alleged NDMA or NDEA impurities in Valsartan API.

Notwithstanding the above, ZHP states that its communications with the FDA related to the recall of Valsartan for potentially containing NDMA or NDEA have been produced through core discovery. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to communications with third parties about the FDA recall of Valsartan or Valsartan API for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 60: ***Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to valsartan contamination, and any related communications.***

RESPONSE TO REQUEST NO. 60: ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period, documents submitted to foreign regulatory agencies, and documents related to health risks other than those alleged in these Actions. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has communicated with numerous foreign regulatory agencies. Therefore, this Request for "all" regulatory documentation in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. Finally, ZHP states that the pharmacovigilance materials sought by way of this Request are irrelevant and inadmissible for any purpose.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to reports of cancer from Valsartan or Valsartan API sold in the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 61: ***Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning valsartan, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof.***

RESPONSE TO REQUEST NO. 61: ZHP incorporates, by reference, its Response to Request No. 60.

REQUEST NO 62: ***Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you.***

RESPONSE TO REQUEST NO. 62: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests documents with no relation to Valsartan, impurities, or injuries at issue in these Actions. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. In addition, Plaintiffs' claims are not based on recalls pursuant to FDA regulations. Therefore, production of documents regarding foreign regulatory agencies is overbroad, unduly burdensome, and not proportional to the needs of the Actions. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has communicated with numerous foreign regulatory agencies. Therefore, this Request for "all" regulatory documentation in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they

never used. Finally, ZHP states that the pharmacovigilance materials sought by way of this Request are irrelevant and inadmissible for any purpose.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to reports of cancer from Valsartan or Vaslartan API sold into the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 63: ***Produce all filings with the Securities and Exchange Commission (SEC), addressing any issues related to the sale of contaminated valsartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.***

RESPONSE TO REQUEST NO. 63: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" filings. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. ZHP also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that its stock is not publicly traded in the United States.

REQUEST NO 64: ***Produce complete documentation of any communications with any state regulatory or health authorities regarding valsartan ingredients, purity, contamination, or pricing.***

RESPONSE TO REQUEST NO. 64: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "any communications" and therefore requires an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to communications with domestic health authorities related to the NDMA or NDEA impurities at issue in this case. ZHP objects to this Request in that the term "state regulatory or health authorities" is vague and

ambiguous and could refer to either the health authorities of the 50 United States, or to foreign authorities.

Notwithstanding the above, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to communications with domestic state health authorities about the NDMA or NDEA recalls for Valsartan or Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 65: ***Produce all documents and communications concerning, with respect to valsartan, all efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs.***

RESPONSE TO REQUEST NO. 65: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents relating to "any" actions and therefore would require an unreasonable search of ZHP's documents. ZHP objects on the basis that it is vague and ambiguous as phrased and, therefore, does not describe with sufficient particularly the materials sought. In fact, as written, this Request could be construed to seek every document or communication related to the development, manufacture, testing, storage, distribution, and labeling of Valsartan API and Valsartan, considering that various cGMPs apply to all aspects of the manufacturing and distribution process. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to cGMPs bearing on the alleged NDMA or NDEA impurities at issue in this case. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, ZHP objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will engage in a meet and confer to more appropriately

define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of these Actions.

XIII. COMPLAINTS AND RECALLS

REQUEST NO 66: ***Produce all documents and communications with regard to any consideration or implementation of a recall due to contamination of valsartan.***

RESPONSE TO REQUEST NO. 66: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to documents related to recalls of Valsartan in the United States Market or to the communications regarding the recalls, products, and alleged NDMA and NDEA impurities at issue in the Actions. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has implemented numerous recalls as a result the potential NDMA and NDEA impurities. Therefore, this Request for "all" documents in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP also objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it requests the production of "all" documents and communications and therefore would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. In addition, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the recalls of Valsartan or Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 67: ***Produce all draft recall notices with regard to contamination of valsartan.***

RESPONSE TO REQUEST NO. 67: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States Market or to the recalls, products, and alleged NDMA or NDEA impurities at issue in the Actions. ZHP sells Valsartan and Valsartan API to customers in 70

countries and has implemented numerous recalls across the world as a result the potential NDMA and NDEA impurities. Therefore, this Request for "all" recall notices in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents and drafts, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. In addition, ZHP will endeavor to produce additional and supplementary non-privileged documents in its possession, if any, related to recalls of Valsartan or Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 68: ***Produce all final recall notices with regard to contamination of valsartan.***

RESPONSE TO REQUEST NO. 68: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States Market or to the recalls, products, and alleged NDMA or NDEA impurities at issue in the Actions. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has implemented numerous recalls around the world as a result the potential NDMA and NDEA impurities. Therefore, this Request for "all" recall notices in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the FDA correspondence produced

over the course of the core discovery process. In addition, ZHP will endeavor to produce additional non-privileged documents in its possession, if any, related to recalls of Valsartan or Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 69: ***Produce all documents and communications relating to or directly with any customer or consumer relating to the recall (or non-recall) of valsartan due to contamination.***

RESPONSE TO REQUEST NO. 69: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States Market or to the recalls, products, and alleged NDMA or NDEA impurities at issue in the Actions. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" communications with all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and unreasonable in that, as written, it seeks documents or information accessible to Plaintiffs from Plaintiffs' own files. ZHP also objects on the basis that the demand for communications relating to a "non-recall" is vague, ambiguous, and potentially overbroad, as it could refer to every communication with any customer about valsartan that did not relate to the recall.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to recalls of Valsartan or Valsartan API for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 70: ***Produce all documents and communications relating to communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.***

RESPONSE TO REQUEST NO. 70: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States Market or to the recalls, products, and alleged NDMA or NDEA impurities at issue in the Actions. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP also objects on the basis that the demand for communications relating to a "non-recall" is vague, ambiguous, and potentially overbroad, as it could refer to every communication with any physician about valsartan that did not relate to the recall.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to recalls of Valsartan or Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 71: ***Produce all documents and communications with any person or entity from or to which you purchased or sold valsartan, with regard to valsartan contamination.***

RESPONSE TO REQUEST NO. 71: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited sales of Valsartan or Valsartan API in the United States Market or to the recalls or alleged NDMA or NDEA impurities at issue in the Actions. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" communications with all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to communications with purchasers of Valsartan and Valsartan API in the United States Market related to recalls of valsartan for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 72: ***Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to valsartan contamination.***

RESPONSE TO REQUEST NO. 72: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of Valsartan or Valsartan API "considered or implemented" in the United States for potentially containing NDMA or NDEA. ZHP sells Valsartan and Valsartan API to customers in 70 countries and has implemented recalls across the world as a result of the potential presence of NDMA or NDEA in Valsartan API. Therefore, this Request for "all" regulatory documentation in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the recall of Valsartan and Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 73: ***Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the quality or purity of valsartan.***

RESPONSE TO REQUEST NO. 73: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan

or Valsartan API sold in the United States Market or to the alleged NDMA or NDEA impurities at issue in the Actions. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" communications with all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP also objects on the basis that "complaint or concern" and "quality" are undefined and ambiguous as phrased, as they could refer to a wide range of activity with no bearing on the issues in these Actions.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the recall of Valsartan and Valsartan API in the United States for potentially containing NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 74: ***Produce all documents and communications concerning any actual or potential import or export alerts relating to valsartan contamination.***

RESPONSE TO REQUEST NO. 74: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to alerts issued by United States agencies related to the alleged NDMA or NDEA impurities at issue in these Actions. ZHP sells Valsartan and Valsartan API to customers in 70 countries, and this Request for "all" documents related to potential import or export alerts in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it includes documents or information publicly

available to the Plaintiffs. In addition, documents that refer and relate to both the Valsartan import alert and FDA warning letter have already been produced as part of core discovery.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to import or export alerts issued by United States agencies related to the alleged NDMA and NDEA impurities in Valsartan and Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 75: ***Produce all documents and communications concerning any refunds that you paid to purchasers of valsartan in the United States from January 1, 2010 to the present, including but not limited to retail pharmacies, direct purchasers, wholesale distributors, and TPPs.***

RESPONSE TO REQUEST NO. 75: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to refunds issued in connection with the recall of Valsartan or the potential presence of NDMA or NDEA. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to refunds ZHP paid to purchasers of Valsartan in the United States for the presence of NDMA or NDEA during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 76: ***Produce all documents and communications regarding recall of valsartan, provided to consumers, physicians, and TPPs, including lists sufficient to show all persons or entities who received communications notifying them of the recall, the contents of all communications contained in the letters notifying persons of the recall, documentation***

tracking all correspondence and communications related to the recall, all drafts of letters or other communications created to notify consumers of the recall.

RESPONSE TO REQUEST NO. 76: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls in the United States for potential NDMA or NDEA impurities. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents and drafts, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request in that it is not limited to "lists" kept by ZHP during the ordinary course of business, and therefore purports to impose on ZHP burdens not authorized by Rule 34.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the recall of Valsartan in the United States for the presence of NDMA or NDEA, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 77: ***Produce all documents relating, referring to or embodying the hiring or retention by any Defendant or by any other person or entity acting on any defendant's behalf, of any public relations firm or any law firm specializing in drug regulatory practices to participate in, orchestrate, organize or otherwise direct any evaluation of recall discussions for valsartan and produce all documents regarding said engagement, including, but not limited to, questions and answer, talk papers, scripts for telephone calls, creation of special advisory or consulting board, gestures to demonstrate concern for victims, donations to causes important to victims, retention of scientific or medical researchers, advisors or experts and other such public relations strategies.***

RESPONSE TO REQUEST NO. 77: ZHP objects on the basis that this Request uses vague, ambiguous, and undefined terms like "evaluation" and, moreover, information relating to "public relations strategies" is irrelevant to the issues presented in these Actions. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of Valsartan API or Valsartan sold in the United States. ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions and requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request in that it seeks documents or information

that are not known or are outside ZHP's possession, custody or control, as it requests "all" documents related to third parties, some of which documents may be in the exclusive control of such third parties.

REQUEST NO 78: ***Produce all documents with regard to, or communications with, Novartis concerning valsartan, including but not limited to, documents or communications relating to testing or evaluation of valsartan, contamination, impurities, recalls, pre-commercial negotiations, contracts (including all draft contracts), product specifications, testing specifications, complaints, responses to complaints, investigations, meeting notes, presentations, and communications with any regulatory authority.***

RESPONSE TO REQUEST NO. 78: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the alleged NDMA or NDEA impurities at issue in these Actions. ZHP further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of "all" documents and drafts, which would require an unreasonable search of ZHP's documents. ZHP further objects to this request as overbroad, unduly burdensome, not proportional, and irrelevant, in that contract negotiations and terms have no bearing on any of Plaintiffs' claims.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to communications with Novartis about the presence of NDMA or NDEA in Valsartan or Valsartan API or the recall of Valsartan in the United States, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

XIV. WARRANTIES AND STATEMENTS

REQUEST NO 79: ***Produce all versions of defendant's labeling for valsartan, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of valsartan.***

RESPONSE TO REQUEST NO. 79: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to labels on Valsartan sold or distributed into the United States Market pursuant to FDA regulations. ZHP sells Valsartan and Valsartan API to customers in 70

countries, and this Request for "all" labels used in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding labels that Plaintiffs and their physicians have never seen. ZHP further objects to this Request as unreasonable in that it is not limited to "charts" that ZHP keeps in the ordinary course of business, and therefore purports to impose burdens on ZHP beyond those authorized by Rule 34. ZHP further objections to this request as unduly burdensome and unreasonable in that it seeks information that is publicly available.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the FDA correspondence and ANDA files produced over the course of the core discovery process, which include information regarding FDA-approved labeling for Valsartan. In addition, subject to the assertions stated here, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to labeling and package inserts for Valsartan API or Valsartan sold into the United States, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 80: ***Documents sufficient to show all (past and present) labels and packaging materials, including all associated documentation and disclosures provided to medical professionals, purchasers, including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States from January 1, 2010 to the present, including copies and drafts of all such materials, and documents sufficient to show the time period during which each exemplar was in use.***

RESPONSE TO REQUEST NO. 80: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and drafts, which would require an unreasonable search of ZHP's documents. ZHP also objects to this request to the extent it seeks information that is publicly available on the FDA website. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks documents predating ZHP's sale of Valsartan into the United States and, therefore, is not limited to the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to the FDA correspondence and

ANDAs produced over the course of the core discovery process, which includes information regarding FDA-approved labeling and package inserts for Valsartan. In addition, subject to the assertions stated here, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to labeling and package inserts for Valsartan API or Valsartan sold into the United States, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 81: ***All advertisements, and sales and marketing material for valsartan utilized from January 1, 2010 to the present, and charts setting forth the approval date, in use dates, and medium (i.e. website, sales document, marketing brochure).***

RESPONSE TO REQUEST NO. 81: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to marketing for Valsartan or Valsartan API sold or distributed into the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" sales materials directed at all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to those parts of this Request that purport to obligate ZHP to create a documentary record—including, for example, "charts"—that does not exist in the ordinary course of business, as it purports to impose burdens on ZHP beyond those authorized by Fed. R. Civ. P. 34. ZHP further objects to the production of "marketing" materials until such time as Plaintiffs identify those documents upon which they or their physicians relied in deciding to prescribe, use, or purchase ZHP's Valsartan.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to product non-privileged documents in its possession, if any, related to marketing of Valsartan or Valsartan API for sale in the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 82: ***Produce final and draft versions of all documents provided to consumers upon purchase of valsartan, (i.e. package inserts, patient brochures).***

RESPONSE TO REQUEST NO. 82: ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and drafts and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to documents provided to purchasers of Valsartan sold in the United States during the Relevant Time Period. ZHP sells Valsartan and Valsartan API to customers in 70 countries, and this Request for "all" labeling and packaging materials used in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials that Plaintiffs acknowledge they never saw. ZHP also objects to this request to the extent it seeks documents or information that is publicly available. ZHP further objects to this Request in that it seeks documents or information that are not known or are outside ZHP's possession, custody or control, because ZHP does not sell Valsartan directly to consumers.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it does not sell Valsartan directly to consumers and refers Plaintiffs to the FDA correspondence and ANDA files produced over the course of the core discovery process, which include information regarding the FDA-approved labeling and package inserts for Valsartan. In addition, subject to the assertions stated here, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to labeling and package inserts for Valsartan API or Valsartan sold into the United States, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 83: ***Produce all communications between you and any medical association concerning any adverse health effects that may or may not or be associated with valsartan.***

RESPONSE TO REQUEST NO. 83: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks the production of "all" documents and therefore would require an unreasonable search of ZHP's documents. ZHP

further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to materials provided to medical associations within the United States during the Relevant Time Period. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the health effects alleged in the complaints in these Actions. Moreover, the Request is ambiguous insofar as it seeks production of communications concerning "adverse health effects" that "may not be associated with valsartan," which is open-ended and all-encompassing.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the risk of cancer from the presence of NDMA and NDEA in Valsartan, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 84: ***Produce documentation of any discussion or submission between Defendant and any medical association concerning any adverse events reported to be associated, regardless of causality, with valsartan.***

RESPONSE TO REQUEST NO. 84: ZHP incorporates, by reference, its Response to Request No. 83.

REQUEST NO 85: ***Produce all communications with financial analysts or investors concerning the role of valsartan in your financial or business prospects, including but not limited to any transcripts, presentations or documents concerning any analyst conference call, or business briefing.***

RESPONSE TO REQUEST NO. 85: ZHP objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that "the role of valsartan" in ZHP's "financial or business prospects" has no bearing on the alleged contamination of Valsartan API with NDMA or NDEA and is not limited to Valsartan and Valsartan API sold into the United States Market. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" communications related to the role of Valsartan or Valsartan API in any market around the world would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this

Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP also objects to this Request as unduly burdensome and unreasonable to the extent it seeks documents or information that is publicly available. ZHP also objects to the extent this Request seeks information predating ZHP's sales of Valsartan in the United States.

REQUEST NO 86: ***Produce all documents and communications evidencing questions from and responses to healthcare providers regarding the safety, quality, recall status, or purity of valsartan from June 1, 2018 to the present.***

RESPONSE TO REQUEST NO. 86: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the Request seeks the production of "all" documents and therefore would require an unreasonable search of ZHP's documents. The Request is also vague and ambiguous insofar as Plaintiffs demand production of documents "evidencing questions." ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to communications with healthcare providers within the United States. ZHP sells Valsartan and Valsartan API to customers in 70 countries, and this Request for communications with healthcare providers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP refers Plaintiffs to FDA's public statements concerning the recalls of Valsartan and the related investigation. In addition, subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to questions ZHP received from healthcare providers regarding the presence of NDEA or NDMA in Valsartan sold into the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 87: ***Produce all documents reflecting public statements made by you regarding valsartan quality, purity, contamination, safety, or manufacturing process,, [sic]***

including but not limited to drafts and final versions of annual reports, press releases, and investor presentations.

RESPONSE TO REQUEST NO. 87: ZHP objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to statements pertaining to alleged contamination of Valsartan API with NDMA or NDEA and requests the production of "all" public statements which are, by definition, equally accessible to Plaintiffs. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to the Relevant Time Period or to statements about Valsartan API or Valsartan sold into the United States Market.

REQUEST NO 88: ***Produce all documents reflecting any communication between you and any consumers, medical professionals, healthcare insurers, PBMs, wholesale distributors, retail pharmacies, investors, analysts, or the media regarding valsartan.***

RESPONSE TO REQUEST NO. 88: ZHP objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and not relevant to any party's claims or defenses in that communications with investors, analysts, and the media have no bearing on any of Plaintiffs' claims. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it seeks the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and not relevant to any party's claims or defenses in that it is not limited to communications regarding Valsartan sold into the United States during the Relevant Time Period related to the alleged NDMA or NDEA impurities. ZHP sells Valsartan and Valsartan API to customers in 70 countries, and this Request for communications with third parties in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding products that Plaintiffs acknowledge they never used. ZHP also objects to this request to the extent it seeks documents or information that is publicly available or otherwise available from another source that is more convenient.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged communications in its possession, if any, regarding the presence of NDMA or NDEA in Valsartan API or Valsartan sold into the United States Market during the Relevant Time Period, which ZHP

will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 89: ***Produce all documents with regard to any policy, procedure, or marketing strategy you used to market, advertise, promote, and/or sell valsartan from January 1, 2010 to the present.***

RESPONSE TO REQUEST NO. 89: ZHP incorporates, by reference, its Response to Request Nos. 31 and 81. ZHP further objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents outside the scope of issues in the present Actions and requests the production of "all" documents in any way relating to "any" unspecified "policy, procedure, or marketing strategy" concerning "valsartan," and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to marketing for Valsartan or Valsartan API sold or distributed into the United States Market. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" sales materials directed at all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to the production of "marketing" materials until such time as Plaintiffs identify those documents upon which they or their physicians relied in deciding to prescribe, use, or purchase ZHP's Valsartan. ZHP also objects to the extent the requested materials are publicly available.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to any marketing by ZHP of Valsartan or Valsartan API in the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 90: ***Produce all documents and communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug***

Enforcement Agency, U.S. Department of Justice, or U.S. Attorney General relating to valsartan contamination.

RESPONSE TO REQUEST NO. 90: ZHP objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the alleged contamination of Valsartan API with NDMA or NDEA and requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, not proportional, and not relevant to any party's claims or defenses in that it seeks information relating to Valsartan marketed outside of the United States and is not limited to the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 91: ***Produce all documents relating to the investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Senate, and/or any other federal or state entity, relating to valsartan contamination, including, but not limited to, the information requested and produced by defendant, as well as communications between the defendant and the federal or state entity which served the subpoenas and/or conducted the investigation.***

RESPONSE TO REQUEST NO. 91: ZHP objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents reflecting communication with a wide swath of persons and entities, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, not proportional, and not relevant to any party's claims or defenses in that it is not limited to documents regarding the alleged NDMA or NDEA impurities.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the presence of NDMA or NDEA in Valsartan or Valsartan API sold into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-

upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 92: ***Produce all documents relating, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning valsartan, including agreements related to reimbursement for valsartan.***

RESPONSE TO REQUEST NO. 92: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, not proportional to the needs of the Actions, and not relevant to any party's claims or defenses in that it is not limited to reimbursements issued in connection with the recall of Valsartan for the potential presence of NDMA or NDEA during the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the presence of NDMA or NDEA in Valsartan or Valsartan API sold in the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

XV. SALE AND DISTRIBUTION

REQUEST NO 93: ***Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for valsartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.***

RESPONSE TO REQUEST NO. 93: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan API and Valsartan purchased, sold, or distributed into the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "complete documentation" of the supply chain for Valsartan, without any limitation to a particular country, would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any

Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it requests the production of "complete documentation," which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside ZHP's possession, custody or control, or are not kept in the ordinary course of business, in that ZHP is not able to determine where or to whom the purchasers of its Valsartan API or Valsartan sell that product. ZHP further objects this Request in that it demands "complete documentation setting forth" certain information, which purports to obligate ZHP to create a documentary record that does not exist in the ordinary course of business, exceeding the burdens authorized by Fed. R. Civ. P. 34. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek documents "demonstrating" the supply chain and therefore does not identify specific documents with reasonable particularity.

By way of further answer, ZHP states as follows:

ZHP does not have documentation "setting forth and/or demonstrating the complete supply and distribution chain for valsartan" through the final sale from a pharmacy to a customer.

REQUEST NO 94: ***Produce all documents relating to the sale and distribution of valsartan that reflect NDC, batch number, and lot number.***

RESPONSE TO REQUEST NO. 94: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed in the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for "all" documents reflecting batch and lot number sold into in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documents relating to" the sale of Valsartan does not identify any particular set of documents and is duplicative of other Requests,

including Requests No. 93, 95, and 99–111; in fact, it is tantamount to a request for every document in ZHP's possession that reflects an NDC, batch, or lot number for Valsartan or Valsartan API, which is facially overbroad, unspecific, and unreasonable.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the sale of Valsartan API and Valsartan into the United States Market during the Relevant Time Period, including documents reflecting the NDC, batch, or lot numbers associated with those sales, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 95: ***Produce documents sufficient to show all sales of valsartan to wholesalers, distributers, retailers, and consumers, including the total net sales, total number of pills and/or units sold, unit price, unit cost, profit margin, and market share by state or territory.***

RESPONSE TO REQUEST NO. 95: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to sales of Valsartan API or Valsartan in the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents sufficient to show "all" sales of Valsartan any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because ZHP's market share and net sales, and the unit price, unit cost, and profit margin for Valsartan API or finished dose at the manufacturer level, are not relevant to showing the price that any consumer paid for Valsartan. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" all sales and therefore does not identify specific documents with reasonable particularity.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to the sale of Valsartan API and Valsartan into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for

responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 96: ***Produce all documentation relating to the due diligence performed (or meant to be performed) in selecting an API or finished dose manufacturer from which you purchased valsartan, including but not limited to policies and procedures.***

RESPONSE TO REQUEST NO. 96: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the purchase or sale of Valsartan API or Valsartan in the United States Market during the Relevant Time Period, and it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it manufactures both Valsartan API and Valsartan and therefore this Request does not apply to ZHP.

REQUEST NO 97: ***Produce all documents and communications from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, ingredients, quality, purity, or contamination relating to valsartan.***

RESPONSE TO REQUEST NO. 97: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the purchase or sale of Valsartan API and Valsartan in the United States Market during the Relevant Time Period, and requests the production of "all documents and communication," which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it seeks documents about the manufacturing process, ingredients, quality, purity, and contamination, without limiting those topics to aspects that are relevant to the alleged NDMA or NDEA impurities in Valsartan API. ZHP further objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that it requests documents related to the finished dose manufacturing process, but Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to communications with holders of approved U.S. ANDAs related

to the presence of NDMA or NDEA in Valsartan or Valsartan API, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 98: ***Produce all documents relating to your decision to purchase valsartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.***

RESPONSE TO REQUEST NO. 98: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the purchase or sale of Valsartan API or Valsartan in the United States Market during the Relevant Time Period, and it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it manufactures both Valsartan API and Valsartan and therefore this Request does not apply to ZHP.

XVI. IDENTIFICATION OF PURCHASERS

REQUEST NO 99: ***Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for valsartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.***

RESPONSE TO REQUEST NO. 99: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" purchasers and therefore does not identify specific documents with reasonable particularity.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it does not sell Valsartan API or Valsartan to TPPs or consumers. In addition, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to sales of Valsartan to purchasers in the United States during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive

documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 100: ***Produce all documents and communications between or among you and any named plaintiff, including consumers and/or TPP entities, including but not limited to MSP Recovery Services (including its assignors, Summacare, Emblem, and Connecticare) and Maine Automobile Dealers Association.***

RESPONSE TO REQUEST NO. 100: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to communications related to Valsartan API or Valsartan or to the recall of Valsartan and requests the production of "all" documents and communications, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests documents and communications that are in Plaintiffs' possession, custody or control.

XVII. SALES AND PRICING

REQUEST NO 101: ***Produce all documents relating to valsartan sales you made in the United States to any purchaser (including, but not limited to, wholesalers, distributors, retailers and retail consumers), including documents that reflect total gross sales, total net sales, total number of units sold, unit price (gross and net), unit cost, cost of goods sold, profit margin, NDC, batch number, and lot number, on an annual basis, by, defendant, state, territory or the District of Colombia.***

RESPONSE TO REQUEST NO. 101: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents related to all Valsartan sales, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that gross sales, net sales, unit price, unit cost, cost of goods sold, and profit margin are not relevant to any potential damages.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that, as part of the ongoing meet-and-confer process, Plaintiffs requested that Defendants consider whether they would be willing to produce certain categories of pricing information, and Defendants have agreed to consider that request. At the same time, Plaintiffs have agreed to reconsider what categories of data they believe they need for purposes of this litigation and, moreover, whether they would be willing to forego their demand

for ancillary information beyond the raw financial data. As noted, the meet-and-confer process is ongoing, and ZHP reserves the right to amend these objections as necessary.

REQUEST NO 102: ***Produce all documents and communications relating to your market share for valsartan, or competition for market share for valsartan, in the United States.***

RESPONSE TO REQUEST NO. 102: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because market share and competition are wholly unrelated to the claims, defenses and issues in the Actions. ZHP also objects to the extent Plaintiffs seek information in their possession, custody, or control or equally accessible to them. ZHP further objects to this Request as vague and ambiguous, insofar as Plaintiffs do not describe with reasonable particularity the documents they seek with regard to "competition for market share."

REQUEST NO 103: ***All documents and communications relating to negotiations over price and terms of sale or distribution between any defendant and any purchaser or re-seller of valsartan.***

RESPONSE TO REQUEST NO. 103: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing negotiations and competition are wholly unrelated to the issues in present Actions. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States Market. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for information about all sales with "any purchaser or re-seller of valsartan" in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed.

REQUEST NO 104: ***Produce all documents and communications relating to any agreements or arrangements between you and any TPP entity (or any person acting on behalf***

of a TPP entity) that did, could, or may affect the quantity or price of valsartan purchased (including e.g., rebate agreements, etc.).

RESPONSE TO REQUEST NO. 104: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States Market. ZHP further objects to this Request as it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that ZHP does not contract directly with any TPPs. ZHP further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions to the extent it requests documents that are in the possession of the Plaintiff TPP entities. ZHP further objects to this Request as vague and ambiguous, insofar as Plaintiffs do not describe with reasonable particularity the documents they seek with regard to information "that did, could, or may affect the quantity or price of valsartan."

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that it is not currently aware of any documents responsive to this request, as it does not contract with any TPPs.

REQUEST NO 105: ***Produce all documents relating to any arrangements between you and any other person or entity that did, could, or may affect the quantity or price of valsartan purchased, including but not limited to rebate agreements.***

RESPONSE TO REQUEST NO. 105: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and would therefore require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because changes in price are wholly unrelated to the issues in present Actions. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to arrangements for sale of Valsartan in the United States Market. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents related to all sales in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or

consumed. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, because Plaintiffs do not define what arrangements "did, could, or may affect the quantity or price of valsartan purchased."

REQUEST NO 106: ***Documents sufficient to identify all retailers and/or sellers (including but not limited to, retail pharmacies, mail order pharmacies) who have offered valsartan for sale in the United States and territories from January 1, 2010 to the present, including but not limited to the name, location, and sales volume for each such retailer, as well as the relevant NDC, Batch Numbers, and Lot Numbers for each seller or retailer, where available.***

RESPONSE TO REQUEST NO. 106: ZHP objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside ZHP's possession, custody or control, or are not kept in the ordinary course of business in that it asks ZHP, a manufacturer located in China, to identify information about "all retailers and/or sellers" of Valsartan in the United States. ZHP simply is not in possession of this information, let alone at the level of detail demanded by Plaintiffs. ZHP also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to identify" all retailers and/or sellers and therefore does not identify specific documents with reasonable particularity.

REQUEST NO 107: ***For each month from January 1, 2010 to the present, produce all documents relating to your actual and projected valsartan sales, including:***

a. ***List price;***
b. ***Average marginal price;***
c. ***Average wholesale price;***
d. ***Wholesale acquisition cost;***
e. ***Direct price;***
f. ***Average discount off of wholesale price or wholesale acquisition cost;***
g. ***Price under Medicare program;***
h. ***Price under Medicaid program;***
i. ***Maximum allowable price;***
j. ***Average manufacturing price (AMP) as defined by, and reported to, the Centers for Medicare and Medicaid Services;***
k. ***Best price, as defined by, and reported to, the Centers for Medicare and Medicaid Services;***
l. ***Net revenue;***
m. ***Gross sales;***
n. ***Net sales;***

o. Units;
p. Gross shipments;
q. All measures of margin, income, earnings, and profits;
r. Unit of volumes sold;
s. Unit of volumes sold net of returns;
t. Total product contribution;
u. All costs and expenses attributable to the product;
v. Sales and distribution cost;
w. Cost of goods sold;
x. Manufacturing costs;
y. Marketing, advertising, promotional, and sales expenses;
z. Depreciable and capital improvements;
aa. Regulatory compliance;
bb. Short-run average variable costs;
cc. Long-run average variable costs;
dd. Fixed costs;
ee. Materials cost;
ff. Labor cost;
gg. Marginal cost;
hh. Rebates, discounts, vouchers, or other product promotions, returns, or charge-backs; and
ii. Coupons or co-pay cards.

RESPONSE TO REQUEST NO. 107: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests an unreasonable level of detail and requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because the cost of production and the prices paid at the manufacturing level are not relevant to any potential damages. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to products manufactured for or sold into the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for extensive and highly detailed data about sales to customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that, as part of the ongoing meet-and-confer

process, Plaintiffs requested that Defendants consider whether they would be willing to produce certain categories of pricing information, and Defendants have agreed to consider that request. At the same time, Plaintiffs have agreed to reconsider what categories of data they believe they need for purposes of this litigation and, moreover, whether they would be willing to forego their demand for ancillary information beyond the raw financial data. As noted, the meet-and-confer process is ongoing, and ZHP reserves the right to amend these objections as necessary.

REQUEST NO 108: ***Documents and communications sufficient to identify every entity that purchased, reimbursed, or compensated you for valsartan from you from January 1, 2010 to the present.***

RESPONSE TO REQUEST NO. 108: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to sales of Valsartan in the United States Market during the Relevant Time Period, and it requests the production of documentation related to "every" entity. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents sufficient to identify all customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" all entities and therefore does not identify specific documents with reasonable particularity.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to sales of Valsartan API or Valsartan sold into the United States Market during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 109: ***Produce all documents relating to contracts for the sale of valsartan from January 1, 2010 to the present including (a) contracts with direct purchasers;***

(b) contracts that provide that the purchaser will take delivery of valsartan from another entity (such as a wholesaler); and (c) contracts concerning or regarding the payment of chargebacks.

RESPONSE TO REQUEST NO. 109: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to contracts for sale of Valsartan in the United States Market during the Relevant Time Period and it requests the production of "all" documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing at the manufacturer level is not relevant to the issues in these Actions.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to contracts for sale of Valsartan to purchasers in the United States during the Relevant Time Period, which documents ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 110: Produce complete documentation of the date, manufacturing source, quantity, and recipient of all samples of valsartan provided by defendant.

RESPONSE TO REQUEST NO. 110: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States Market and it requests the production of "complete" documentation, which would require an unreasonable search of ZHP's documents. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents related to customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request on the grounds that the term "sample" is vague, ambiguous, and lacking in particularity. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it seeks information about Valsartan "samples" that is not limited to the NDMA or NDEA impurities at issue in these Actions. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating the Relevant Time Period.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to samples of Valsartan API it provided to any holders of approved U.S. ANDAs during the Relevant Time Period, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 111: ***Produce all electronic data in tab-delimited, comma-delimited, or semicolon-delimited ASCII flat text or similar electronic format from January 1, 2010 to the present sufficient to identify all sales of valsartan to purchasers in transaction-by-transaction format, as follows:***

a. ***All direct sales/invoice transactions (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold, (iv) number of units returned or otherwise affected by the transaction, (v) unit of measure, (vi) date of transaction, (vii) information sufficient to identify the type of transaction (e.g., a sale, a return, a discount, etc.), (viii) NDC, (ix) UPC, (x) SKU, (xi) product description, (xii) product form, (xiii) strength, (xiv) package size in extended units per package, (xv) customer name, (xvi) customer number, (xvii) customer address, (xviii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to and ship-to customer), and (xix) the customer's parent company (if the data identifies a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse, or the like).***

b. ***All data concerning chargebacks, rebates, discounts, and other consideration given or accrued relating to valsartan, including the following fields: (i) each transaction, including the date thereof; (ii) the name and address of, and all unique codes or identifiers for, the person, firm corporation, or other business entity whom you paid, or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration; (iii) the name and address of, and all unique codes or identifiers for, the persons, firms, corporations, or other business entities that made the purchases in respect of which you paid or accrued the chargeback, rebate, discount, or other consideration; (iv) the sales, or groups of sales, upon which the rebate, discount, or other consideration is based, including: (aa) the number of units of the particular product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers for each sale or other transaction; (bb) the bill-to customer; (cc) the ship-to customer; (dd) the dates of the sales, or group of sales; (ee) the invoice amount in dollars for the sales or group of sales; (ff) the amount of the chargeback, rebate, discount, or other consideration paid or accrued; and (gg) the contract, agreement, or other basis upon which the chargeback, rebate, discount, or other consideration is calculated.***

c. ***All administrative fee transactions relating to valsartan, including: (i) fee amount paid, (ii) date of payment, (iii) date or date range of sales concerning the fee that***

was paid, (iv) information sufficient to identify the type of administrative fee (if applicable), (v) customer name, (vi) customer number, (vii) customer address, and (viii) customer class of trade code and the description of that code;

d. For all other transaction types not reflected in (a) through (c) above, produce all documents relating to any other paid or accrued discounts, rebates, chargebacks, billbacks, unit adjustments, price adjustments, shelf-stock price adjustments, returns, third-party returns, error corrections, free goods, nominally-priced goods, whether created or maintained daily, monthly, quarterly, or at some other periodicity, with regard to valsartan.

e. The complete documentation for all items above (a though d) including (i) lookup tables, (ii) data dictionaries, (iii) lists of fields, (iv) descriptions of information contained in those fields (e.g., field lengths, formats, etc.), and (v) descriptions of any codes used in any fields (such as class of trade designations, etc.), including but not limited to (aa) a separate product list, including NDC, SKU, UPC, product description, and package size; (bb) a separate table that lists, for each "bill-to customer" and "shipto customer," the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (e.g., SIC code); (cc) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating (1) whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect net quantity sold and (2) how negative unit and dollar values should be treated in calculating net quantities and dollar amounts; (dd) all data sets and calculations used to (1) determine accrued rebates and/or chargebacks and/or (2) periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks; (vi) return and/or exchange policies; and (vii) payment terms.

RESPONSE TO REQUEST NO. 111: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for extensive and highly detailed data about sales to customers in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing and costs at the manufacturer level is not relevant to the issues in these Actions. ZHP further objects to this Request to the extent

it requests data in formats and charts that ZHP does not maintain in the ordinary course of business, which imposes burdens on ZHP beyond those authorized by Rule 34.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP states that, as part of the ongoing meet-and-confer process, Plaintiffs requested that Defendants consider whether they would be willing to produce certain categories of pricing information, and Defendants have agreed to consider that request. At the same time, Plaintiffs have agreed to reconsider what categories of data they believe they need for purposes of this litigation and, moreover, whether they would be willing to forego their demand for ancillary information beyond the raw financial data. As noted, the meet-and-confer process is ongoing, and ZHP reserves the right to amend these objections as necessary.

XVIII. AVAILABLE DATA SOURCES

REQUEST NO 112: ***Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, PriceCheck, ImpactRx, First DataBank, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding valsartan.***

RESPONSE TO REQUEST NO. 112: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States Market or the Relevant Time Period and requests the production of "all" documents. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for data about sales in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request to the extent it seeks to have ZHP pull documents or data from subscription services that ZHP does not keep in the ordinary course of business. ZHP also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to data that ZHP maintains in the ordinary course of business from the above sources applicable to the United States Market, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon

custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 113: ***Produce all data or reports generated by IMS, CMS, or Verispan, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, prescription, marketing, promotion, or detailing of valsartan from date of launch to the present for valsartan, including:***

- ***a. IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.***
- ***b. IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.***
- ***c. CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to valsartan.***
- ***d. Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to valsartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.***

RESPONSE TO REQUEST NO. 113: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States Market or the Relevant Time Period and requests the production of "all" documents. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents related to sales in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed. ZHP further objects to this Request to the extent it seeks to have ZHP pull documents or data from subscription services that ZHP does not keep in the ordinary course of business. ZHP also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to data relevant to the United States Market that ZHP maintains in the ordinary course of business from the above sources, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon

custodial files, and/or from databases where responsive documents are reasonably expected to reside.

REQUEST NO 114: ***Produce all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.***

RESPONSE TO REQUEST NO. 114: ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents, which would require an unreasonable search of ZHP's documents. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents related to "any" coupon or co-pay assistance, not just coupons or reimbursements offered as a result of the potential presence of NDMA or NDEA in Valsartan. ZHP further objects to this Request as it seeks documents or information that are not known or are outside ZHP's possession, custody or control, in that ZHP does not sell Valsartan directly to consumers. ZHP further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States Market during the Relevant Time Period. ZHP sells Valsartan or Valsartan API to 280 customers in 70 countries. Therefore, this Request for documents related to any reimbursements in any country would require ZHP to search for, collect, and review voluminous documents irrelevant to any of Plaintiffs' claims. There is no justification for this sprawling discovery demand for information regarding materials completely unrelated to any Valsartan that Plaintiffs purchased or consumed.

Notwithstanding the above, and subject to the objections asserted herein and to the Court's ruling on the Macro Discovery Issues, ZHP will endeavor to produce non-privileged documents in its possession, if any, related to reimbursements ZHP offered to consumers because of the presence of NDMA or NDEA in Valsartan, which ZHP will identify through a reasonable search for responsive documents using agreed-upon search terms and agreed-upon custodial files, and/or from databases where responsive documents are reasonably expected to reside.

Dated: November 18, 2019

Respectfully submitted,

DUANE MORRIS LLP

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CERTIFICATE OF SERVICE

I certify that on November 18, 2019, I served the foregoing document on Plaintiffs' Co-Lead and Liaison Counsel via electronic mail.

/s/ Seth A. Goldberg

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